



# The Anticompetitive Impact of Settlements in the Pharmaceutical Industry: The Need for Revisions to the Drug Price Competition and Patent Restoration Act of 1984

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# **The Anticompetitive Impact of Patent Settlementsin the Pharm**

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The Anticompetitive Impact of Patent Settlements  
in the Pharmaceutical Industry:  
The Need for Revisions to the Drug Price Competition and Patent Restoration Act of 1984

Claire G. Kunstling

## I.

### Introduction

Over the next four years, patents on innovator drugs<sup>1</sup> with combined United States sales of almost twenty billions dollars will expire.<sup>2</sup> Once these patents expire, the manufacturers of these drugs will no longer enjoy government protected market exclusivity. Generic drug companies<sup>3</sup> will be free to introduce their own versions of the innovator drugs into the market. Because pharmacists usually are permitted to substitute lower-priced generic versions for innovator drugs, and in some cases are even required to do so, the introduction of these generic drugs will likely have quite an impact on the market.<sup>4</sup> And, since generic companies typically charge less for their version of the innovator drugs, entry by generic drug companies is likely to result in remarkable

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<sup>1</sup>An “innovator” or “pioneer” drug is a drug that has patent protection for either its chemical formulation or its manufacturing process, has gone through the extensive FDA approval process, and is marketed under a brand name. *See* CONGRESSIONAL BUDGET OFFICE STUDY, HOW INCREASED COMPETITION FROM GENERIC DRUGS HAS AFFECTED PRICES AND RETURNS IN THE PHARMACEUTICAL INDUSTRY (July 1998), *available at* <http://www.cbo.gov> [hereinafter CBO STUDY]. The terms “innovator” and “pioneer” will be interchangeably in this paper.

<sup>2</sup>*See* Timothy J. Muris, Prepared Statement of the Federal Trade Commission Before the Senate Committee on Commerce, Science, and Transportation (April 23, 2002), *available at* <http://www.ftc.gov/os/2002/04/pharmtestimony.htm>.

<sup>3</sup>A “generic” drug is a replica of an innovator drug that contains the same active ingredients as the innovator drug and that the FDA judges to be comparable to the innovator drug in terms quality, strength, and therapeutic effectiveness. If a generic drug relies on a patent held by the innovator drug, the generic cannot receive FDA approval to enter the market until the patent on the innovator has expired. *See* CBO STUDY, *supra* note 1.

<sup>4</sup>*See* Analysis to Aid Public Comment at 2, In the Matter of Schering-Plough Corp., Upsher-Smith Labs., and American Home Products Corp. (Feb. 19, 2002) (FTC Dkt. No. 9297) [hereinafter Schering Analysis], *available at* <http://www.ftc.gov/os/2002/02/ahanalysis.htm>. Many third-party payers of prescription drugs support the use of or even demand the use of generic versions of innovator drugs thus further increasing the impact that generics have on the market. *See id.*

cost savings for consumers. While this phenomenon should benefit both consumers and manufacturers of generic drugs, manufacturers of innovator drugs could potentially see a significant drop in profits due to this increased competition.

As innovator drug companies face the prospect of earning decreased profits for many of their top sellers, they have increasingly looked for new ways to extend the patent life on these drugs. One of the ways that pioneer drug companies typically extend the patent life of their drugs is to take advantage of the patent term extensions provided for under the Drug Price Competition and Patent Restoration Act of 1984, commonly known as the Hatch-Waxman Act. However, for companies that have already taken advantage of all of the patent extension time for which they are eligible, generic entry seems inevitable. Increasingly, however, companies are finding ways to exploit loopholes in the regulatory structure established by the Hatch-Waxman Act in order to maintain their market exclusivity. In recent years, one of the primary ways that pharmaceutical companies have manipulated the Hatch-Waxman Act's regulatory structure is to enter into patent settlements with generic companies who challenge their patents under provisions of the Act. These settlements, which may end up blocking entry by *all* generics, not just the generic involved in the patent litigation case, usually enable pioneer drug companies to extend market exclusivity beyond the patent life of their drugs. While both the pioneer drug companies and the generic drug companies typically profit from these settlements, the loss of potential competition is frequently quite costly to consumers.

Many people attribute the United States' position as the world leader in the pharmaceutical industry to the innovation encouraged under the intellectual property laws and the competition fostered by the antitrust regime.<sup>5</sup> However, patent settlements have the potential to distort the incentives created by both of these regimes and interfere with their proper functioning. Patent settlements within the pharmaceutical industry have the potential to distort these incentives even more because of their interplay with certain provisions

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<sup>5</sup>See David A. Balto, *Pharmaceutical Patent Settlements: The Antitrust Risks*, 55 FOOD DRUG L.J. 321, 324 (2000).

in the Hatch-Waxman Act. Therefore, even though the settlement of litigation is generally favored in this country, patent settlements within the pharmaceutical industry are generally not favorably looked upon by policymakers or by law enforcement officials.

This paper will begin by briefly examining the theories behind antitrust law and intellectual property law. Then it will look at the provisions of the Hatch-Waxman Act and at how Congress tried to balance the incentives underlying both of these regimes within those provisions. The paper will continue by looking at the costs and benefits of settlements, particularly patent settlements in the pharmaceutical industry. The paper will then examine three cases filed by the Federal Trade Commission (FTC) challenging patent settlements between pioneer drug companies and generic drug companies. Because of the impact that these types of settlements may have on consumers, numerous proposals for reform of the Hatch-Waxman Act have been made. The paper will conclude by addressing those proposals and offering an analysis as to which proposals are most likely to benefit consumers in the long run.

## II.

### The Relevant Background Law

#### A.

##### Intellectual Property Law

The primary purpose of the intellectual property laws is to promote innovation.<sup>6</sup> One of the ways that the intellectual property laws encourage innovation is by allowing inventors to obtain patents, which are essentially government-protected monopolies over their inventions that last for seventeen years.<sup>7</sup> These government-protected monopolies are essential to promoting innovation because of the large fixed costs associated with creating products and services based on intellectual property.<sup>8</sup> In the absence of intellectual property laws, competitors would decrease the inventor's return on the investment by free riding on his ideas.<sup>9</sup> The result of this free riding would be that many products that increase public welfare would never be able to enter the market because the inventor could not afford the large initial investment.<sup>10</sup> Even though products and

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<sup>6</sup>See U.S. DEPARTMENT OF JUSTICE AND THE FEDERAL TRADE COMMISSION, ANTITRUST GUIDELINES FOR THE LICENSING OF INTELLECTUAL PROPERTY, §1.0 (Apr. 6, 1995) (noting that the goal of intellectual property law is to “provide incentives for innovation and its dissemination and commercialization by establishing enforceable property rights for the creators of new and useful products, more efficient processes, and original works of expression.”), *available at* <http://www.usdoj.gov/atr/public/guidelines/ipguide.htm>. [hereinafter GUIDELINES]

<sup>7</sup>See 35 U.S.C. §154 (2001). The Second Circuit has noted that “the patent laws reward the inventor with a temporary monopoly that insulates him from competitive exploitation of his patented art.” *SCM Corp. v. Xerox Corp.*, 645 F.2d 1195 (2d Cir. 1981), *cert. denied*, 455 U.S. 1016 (1982).

<sup>8</sup>See Robert Pitofsky, Chairman of the Federal Trade Commission, Antitrust and Intellectual Property: Unresolved Issues at the Heart of the New Economy, Prepared Remarks for the Antitrust, Technology, and Intellectual Property Conference (March 2, 2001), *available at* <http://www.ftc.gov/speeches/pitofsky/ipf301.htm>.

<sup>9</sup>See Richard A. Posner, Antitrust in the New Economy, Presented to the American Law Institute-ABA Commission on Continuing Professional Education (Sept. 14, 2000), *available at* [http://www.ali-aba.org/aliaba/Posner\\_101100.htm](http://www.ali-aba.org/aliaba/Posner_101100.htm).

<sup>10</sup>See *id.*

services based on intellectual property frequently require large initial investments, the marginal cost of creating additional copies of the invention is usually quite low in comparison.<sup>11</sup>In principle, the expected profits from sales of these additional copies of an invention while it is under patent warrant the risk the inventor takes when making the initial investment. The value of patent protection, then, comes from the additional returns that an inventor is able to make over and above the returns that he could make in the absence of the patent.<sup>12</sup>Thus, the intellectual property laws encourage inventors to make the large initial investments necessary for innovation by creating a government-protected monopoly and then allowing the patent holder to recoup his investment by enforcing this monopoly against potential competitors.<sup>13</sup> However, by protecting economic profits, the patent system sometimes does more than encourage innovation. In some cases, the patent system also encourages harmful monopolistic behavior and collusive activities among competitors or potential competitors.

Intellectual property protection is quite important to the pharmaceutical industry. In fact, in a survey of one hundred United States firms in differing industries, drug companies indicated that sixty-five percent of their drugs would not have been developed or commercially introduced in the absence of patent protection.<sup>14</sup>One of the primary reasons why intellectual property laws are important to the pharmaceutical industry is because the development of new drugs, like the development of most other products reliant upon intellectual property, requires a large initial investment. According to a recent estimate by the Boston Consulting Group,

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<sup>11</sup>See Pitofsky, *supra* note 8.

<sup>12</sup>See Jean Olson Lanjouw, *Patent Protection in the Shadow of Infringement: Simulation Estimations of Patent Value*, 65 REV. ECON. STUD. 671, 671 (1998).

<sup>13</sup>See PHILLIP AREEDA AND LOUIS KAPLOW, ANTITRUST ANALYSIS: PROBLEMS, TEXT, CASES 415 (Aspen Law and Business 5<sup>th</sup> ed. 1997).

<sup>14</sup>See PHARM. RESEARCH AND MFRS OF AM., PHARMACEUTICAL INDUSTRY PROFILE (2000) (citing C.E. Barfield & C. Beltz., *Balancing and Rebalancing the National Interest in the Patent System*, AM. ENTER. INST. (October 1995)). This figure is much higher than was reported by any other industry in the study. See *id.*

the pre-tax cost of developing a drug introduced in 1990 was \$500 million.<sup>15</sup> A more recent study by the Tufts Center for the Study of Drug Development indicates that the cost of developing a new drug has risen to about \$802 million.<sup>16</sup> The industry as a whole is estimated to have allocated \$26.4 billion, about 20.3% of sales, to research and development in the year 2000.<sup>17</sup> In an industry characterized by such large investments in research and development, the intellectual property laws are essential if drug companies are to earn enough profits to recoup their investments.

The large investments in research and development could, by themselves, have a chilling effect on innovation, but in the pharmaceutical industry the effect is compounded by the long period of time that it takes to bring a new drug to market. During the 1990's, the average drug took almost fifteen years to develop.<sup>18</sup> During these fifteen years, companies were not able to realize any returns on their huge initial investment. To make matters even worse, only three out of every ten new drugs introduced has economic returns that are higher than their average after-tax research and development costs.<sup>19</sup> Despite the high costs, delay in realizing returns, and low chance of profitability, once a successful drug is developed, it is usually relatively easy and inexpensive to reproduce.<sup>20</sup> This means that once a drug has actually been developed and is ready to be marketed, it has the potential to be quite profitable. Studies have estimated that for drugs introduced in the early 1980's, the earned returns exceeded the capitalized costs of development by \$22 million to \$36

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<sup>15</sup>See *id.* (citing BOSTON CONSULTING GROUP, THE CONTRIBUTION OF PHARMACEUTICAL COMPANIES: WHAT'S AT STAKE FOR AMERICA (September 1993)). This figure includes the cost of research failures and the interest costs over the period of investment. See *id.*

<sup>16</sup>See Lewis Krauskopf, *More Challenging Growth Goals Make Drug Mergers Likely, Experts Say*, THE RECORD (NEW JERSEY), Dec. 30, 2001.

<sup>17</sup>See PHARM. RESEARCH AND MFRS OF AM., *supra* note 14 (citing J.A. DiMasi, *New Drug Development: Cost, Risk, and Complexity*, DRUG INFORMATION JOURNAL (May 1995)).

<sup>18</sup>See *id.*

<sup>19</sup>See CBO STUDY, *supra* note 1.

<sup>20</sup>See *id.*



million on average.<sup>21</sup> Thus, intellectual property protection is important to the pharmaceutical industry because it provides innovator drug manufacturers with a period of market exclusivity during which they are able to earn these profits. This period of market exclusivity allows the companies to recoup their large initial investments and generate the funds they need in order to do more research and development in the future.

## B.

### Antitrust Law

The primary purpose of the antitrust laws is to promote competition.<sup>22</sup> There are numerous rationales as to why it is necessary to protect competition. Some theorists believe that it is important to protect competition because it can have positive effects on economic efficiency and consumer welfare.<sup>23</sup> Others believe that competition is beneficial because it helps preserve opportunities for smaller firms.<sup>24</sup> Some subscribe to the view that competition is beneficial because it prevents unfair redistribution of wealth from consumers to producers.<sup>25</sup> Many support some combination of these rationales. Regardless of the rationale to which they subscribe, all those who enforce the antitrust laws are concerned with preventing unreasonable restraints

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<sup>21</sup> See *id.* This figure is based on an estimate that manufacturers invest an average of about \$200 million (in 1990 dollars) to bring a new drug to market. The CBO estimates that since 1984, the expected level of returns from marketing a brand name drug has dropped by twelve percent, or an average of twenty-seven million dollars. See *id.*

<sup>22</sup> See AREEDA, *supra* note 13, at 415.

<sup>23</sup> See *id.*

<sup>24</sup> See *id.*

<sup>25</sup> See *id.*

on trade that have the effect of diminishing competition.<sup>26</sup> There are several major antitrust provisions that are relevant for the purposes of this paper. Briefly, Section 1 of the Sherman Act makes all contracts, combinations, and conspiracies that restrain trade illegal.<sup>27</sup> Section 2 of the Sherman Act makes the act of monopolizing, attempting to monopolize, or conspiring to monopolize illegal.<sup>28</sup> Finally, Section 5 of the Federal Trade Commission Act makes unfair methods of competition and unfair or deceptive acts or practices illegal.<sup>29</sup> When enforcing these laws, actual written agreements between competitors or potential competitors often serve as red flags to antitrust authorities. Two types of agreements prove to be particularly problematic. The first type are those under which parties agree not to compete along some important dimension such as price, quality, or innovation, or in some particular geographic region or product market, or even not to compete at all.<sup>30</sup> The second type are those in which parties work together to keep other competitors from entering the market or from succeeding in the market by denying them access to a means of competing in the market or by outright refusing to deal with them.<sup>31</sup> As will be discussed later in this paper, patent settlements in the pharmaceutical industry are problematic for antitrust enforcers because they often take the form of one or both of these types of anticompetitive agreements.

The protections provided to pharmaceutical companies by the antitrust laws are particularly important because many of the same factors that inhibit innovation in the pharmaceutical industry also hinder competition in the pharmaceutical industry. One of the biggest impediments to competition in the pharmaceutical

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<sup>26</sup>See Balto, *supra* note 5, at 326.

<sup>27</sup>See 15 U.S.C. §1 (2001).

<sup>28</sup>See 15 U.S.C. §2 (2001).

<sup>29</sup>See 15 U.S.C. §45 (2001). It should be noted that while the FTC Act covers a broader spectrum of activities than the Sherman Act, it can only be enforced by the FTC.

<sup>30</sup>See Balto, *supra* note 5, at 327.

<sup>31</sup>See *id.*

industry is the large amount of money needed for research and development.<sup>32</sup> Many potential entrants are kept out of the market because they simply cannot raise the capital that is needed in order to successfully discover, develop, manufacture, and seek approval with the Food and Drug Administration (FDA) for a new drug. Another obstacle for potential competitors is the long amount of time required to complete the development process.<sup>33</sup> Even if a potential entrant can raise initial capital, it may not be able to sustain itself for the fifteen years that it could take to see any sort of profit on a new drug. Finally, patent protection itself serves as a hurdle for potential entrants because depending on the patent, potential competitors may be prevented from using a particular method of manufacturing or from using a discovery in the same manner as the patent holder. Given the negative impact that these factors alone have on competition, the antitrust laws are necessary to prevent the types of agreements and other anticompetitive practices that would serve to further stifle competition in the industry.

## C.

### The Tension Between Intellectual Property Law and Antitrust Law

In many ways, the intellectual property laws and the antitrust laws embody complementary principles. At their core, both sets of laws are rooted in the fundamental public policy of benefiting society - the intellectual property laws by promoting innovation and the antitrust laws by protecting competition.<sup>34</sup> Both

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<sup>32</sup>See *supra* notes 15 - 17 and accompanying text.

<sup>33</sup>See *supra* note 18 and accompanying text.

<sup>34</sup>See Balto, *supra* note 5, at 415. As the Federal Circuit has noted, “[t]he aims and objectives of patent and antitrust laws may seem, at first glance, wholly at odds. However, the two bodies of law are complementary, as both are aimed at encouraging innovation, industry and competition.” *Atari Games Corp. v. Nintendo of America, Inc.*, 897 F.2d 1572, 1576 (Fed. Cir. 1990) (citing *Loctite Corp. v. Ultraseal Ltd.*, 781 F.2d 861, 876-77 (Fed. Cir. 1985))

regimes acknowledge that the market does not operate perfectly and must be monitored in order to prevent market abuses that can harm society.<sup>35</sup> Ultimately, the two sets of laws also are alike in that they recognize that the behaviors they promote can be harmful to society and must be balanced with other interests.<sup>36</sup> Despite these similarities, the intellectual property laws and the antitrust laws often come into conflict. This conflict arises because the protection provided to inventors under the intellectual property laws may prevent the types of competition that the antitrust laws try to protect.<sup>37</sup> Since patents give their holders what essentially amounts to a government-protected monopoly, patents may harm competition by making it difficult for a potential competitor to enter the market without infringing on the patent.<sup>38</sup> Patents may also stifle competition by discouraging research into improved products that could beat out the competition since improving a product without infringing a patent may be impossible.<sup>39</sup> Because of these harmful effects on competition, many of the social costs of a monopoly that the antitrust laws seek to prevent, such as reduced output, higher prices, and underutilization of knowledge, occur in markets dependent on patented products.<sup>40</sup>

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<sup>35</sup> See Balto, *supra* note 5, at 416.

<sup>36</sup> See *id.*

<sup>37</sup> According to the Second Circuit:

The conflict between the antitrust laws and patent laws arises in the methods they embrace that were designed to achieve reciprocal goals. While the antitrust laws proscribe unreasonable restraints of competition, the patent laws reward the inventor with a temporary monopoly that insulates him from competitive exploitation of his patented art. When the patented product, as is often the case, represents merely one of many products that effectively compete in a given product market, few antitrust problems arise. When, however, the patented product is so successful that it evolves into its own economic market, as was the case here, or succeeds in engulfing a large section of a preexisting product market, the patent and antitrust laws necessarily clash. In such cases the primary purpose of antitrust laws – to preserve competition – can be frustrated, albeit temporarily, by a holder's exercise of the patent's exclusionary power during its term.

SCM Corp. v. Xerox Corp., 645 F.2d 1195, 1203 (2d Cir. 1981), *cert. denied*, 455 U.S. 1016 (1982).

<sup>38</sup> See AREEDA, *supra* note 13, at 151.

<sup>39</sup> See *id.* at 151.

<sup>40</sup> See *id.* at 150.

In recent years, the federal antitrust authorities have increasingly addressed the conflict between the antitrust laws and intellectual property laws. In 1995, the FTC and the Department of Justice jointly issued the *Antitrust Guidelines for the Licensing of Intellectual Property*. The overall approach of these guidelines embodies three general principles that should be kept in mind when addressing situations involving the interplay between the antitrust laws and the intellectual property laws. First, antitrust enforcers should apply the same antitrust principles to conduct involving intellectual property as they would to conduct involving any other form of property.<sup>41</sup> The agencies recognize that intellectual property has certain important characteristics that distinguish it from other types of property and take these differences into account in cases involving intellectual property, however, the governing antitrust principles are the same.<sup>42</sup> Second, the antitrust enforcers do not assume that intellectual property creates market power for the purposes of antitrust analysis.<sup>43</sup> Even though intellectual property rights confer the right to exclude, there are often other substitutes for the product that will diminish market power.<sup>44</sup> Even if intellectual property rights do confer market power, that market power does not offend the antitrust laws by itself.<sup>45</sup> Third, the antitrust enforcers recognize that intellectual property licensing can be pro-competitive.<sup>46</sup> Licensing may expand access to intellectual property and make the process of bringing new products to market more efficient.<sup>47</sup> Thus, despite the fact that the two sets of laws cannot be entirely reconciled, the agencies in charge of enforcing the antitrust laws have provided some guidance for those trying to predict whether they will challenge as

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<sup>41</sup> See GUIDELINES, *supra* note 6, at §2.1.

<sup>42</sup> See *id.*

<sup>43</sup> See *id.* at §2.2.

<sup>44</sup> See *id.*

<sup>45</sup> See *id.*

<sup>46</sup> See *id.* at §2.3.

<sup>47</sup> See *id.*

anticompetitive a practice involving intellectual property.

Perhaps nowhere is the conflict between the intellectual property laws and the antitrust laws more evident than in the pharmaceutical industry. Intellectual property law plays an important role in insuring that pharmaceutical companies are able to afford the research and development process that leads to beneficial new drugs for consumers and profits for the drug companies. At the same time, as pharmaceutical costs continue to rise, antitrust laws play an important role in insuring that pharmaceutical companies continue to compete in terms of price and in terms of beneficial new products. The challenge for lawmakers has been to try and find the proper balance in the pharmaceutical industry between the intellectual property laws and the antitrust laws.

### **III.**

## **The Drug Price Competition and Patent Restoration Act of 1984**

### **A.**

#### **Historical Context**

The complex interplay between the antitrust laws and the intellectual property laws is even more complicated in the pharmaceutical industry because of the regulatory scheme created under the Hatch-Waxman Act. The Hatch-Waxman Act, was passed in response to several of the effects that the 1962 Amendments to

the Federal Food, Drug, and Cosmetic Act (“FDCA”) had on the pharmaceutical industry. Before passage of the 1962 Amendments, pharmaceutical manufacturers seeking FDA approval of a new drug only had to prove that their drug was safe.<sup>48</sup> However in response to the Thalidomide tragedy of 1961, Congress enacted the 1962 Amendments which added the additional requirement that all new drugs also had to demonstrate effectiveness.<sup>49</sup> In order to obtain FDA approval under this new standard, pioneer drug companies had to submit human test results demonstrating both safety and effectiveness as a part of their New Drug Applications (NDAs).<sup>50</sup> The practical effect of this additional requirement was a significant increase in the scientific, technical, and administrative burdens on pioneer drug manufacturers seeking FDA approval of a new drug through an NDA.<sup>51</sup> In addition to adding an efficacy requirement for innovator drugs, the 1962 Amendments also established alternative FDA approval procedures for certain generic drug manufacturers. Under the 1962 Amendments, drug manufacturers seeking FDA approval for generic equivalents of pioneer drugs which had been approved by the FDA prior to 1962 did not have to perform all of the human clinical tests that are required for an NDA.<sup>52</sup> Instead, generic drug manufacturers could submit an Abbreviated New Drug Application (ANDA) containing test results which demonstrated that the generic drug was the same as the drug produced by the pioneer and contained assurances that the generic would be properly manufactured and labeled.<sup>53</sup> The rationale behind the abbreviated procedure was twofold. First, the FDA viewed such retesting as inefficient and unnecessary since the pioneer drug had already been determined to be safe and

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<sup>48</sup>See H.R. REP. NO. 98-857(I), at 16 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2649. See also Gerald J. Mossinghoff, *Striking the Right Balance Between Innovation and Drug Price Competition: Understanding the Hatch-Waxman Act: Overview of Hatch-Waxman Act and Its Impact on the Drug Development Process*, 54 FOOD DRUG L.J. 187, 187 (1999).

<sup>49</sup>See Mossinghoff, *supra* note 48, at 187.

<sup>50</sup>See H.R. REP. NO. 98-857(I), *supra* note 48, at 16.

<sup>51</sup>See Kleinfeld, Kaplan, & Becker, *Human Drug Regulation: Comprehensiveness Breeds Complexity*, in FOOD AND DRUG LAW 243, 245 (Richard M. Cooper ed., 1991).

<sup>52</sup>See H.R. REP. NO. 98-857(I), *supra* note 48, at 16.

<sup>53</sup>See *id.*

effective.<sup>54</sup>Second, the FDA also felt that such retesting was unethical because it meant that a certain number of sick patients would be given placebos, thus denying patients a treatment known to be effective.<sup>55</sup>Despite the fact that these rationales were equally applicable to post-1962 drugs, the 1962 Amendments made no provision for an abbreviated approval process for generic versions of post-1962 drugs.

The 1962 Amendments sought to benefit consumers by reducing the costs imposed on society by ineffective drugs, but the additional burdens imposed by the amendments had two significant, unintentional adverse effects on the pharmaceutical industry. First, the strict efficacy requirements mandated by the 1962 Amendments increased the amount of time it took for a drug manufacturer to get FDA approval.<sup>56</sup>Since drug manufacturers usually obtain patent approval before submitting their NDA to the FDA, this longer approval period led to a significant loss of effective patent life for pioneer drugs.<sup>57</sup>Second, because the 1962 Amendments made it more difficult to obtain approval of an NDA and because the ANDA procedure was only applicable to pre-1962 drugs, the NDA requirements had the practical effect of preserving market exclusivity for innovator drugs by stalling, and even preventing, the development of generic versions of post-1962 drugs.<sup>58</sup>In fact, at the time the Hatch-Waxman Act was enacted, there were around 150 post-1962 drugs off patent for which there were no generic equivalents.<sup>59</sup>

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<sup>54</sup>*See id.*

<sup>55</sup>*See id.*

<sup>56</sup>*See* ALLAN M. FOX & ALAN R. BENNETT, THE LEGISLATIVE HISTORY OF THE DRUG PRICE COMPETITION AND RESTORATION ACT OF 1984 iii (Food and Drug Law Institute Series 1987). Currently, it takes an average of nine years to obtain FDA approval to bring a new pioneer drug to market. *See* ROBERT LEVY, FED. TRADE COMM'N., BUREAU OF ECONOMICS STAFF REPORT, THE PHARMACEUTICAL INDUSTRY: A DISCUSSION OF COMPETITIVE AND ANTITRUST ISSUES IN AN ENVIRONMENT OF CHANGE (Mar. 1999).

<sup>57</sup>*See id.*

<sup>58</sup>*See id.*

<sup>59</sup>*See* H.R. REP. NO. 98-857(I), *supra* note 48, at 17.



B.

## Statutory Provisions

The Hatch-Waxman Act sought to deal with the unintended effects of the 1962 Amendments by striking a compromise between protection of the interests of the generic drug manufacturers and protection of those of the innovator drug manufacturers. The purpose of the Act was twofold. Congress wanted “to make available more low cost generic drugs by establishing a generic drug approval procedure for pioneer drugs first approved after 1962” while at the same time “creat[ing] a new incentive for increased expenditures for research and development of certain products which are subject to premarket government approval.”<sup>60</sup> Thus, from a policy perspective, the Act was basically an attempt to balance the same goals as those embodied within the antitrust laws and the intellectual property laws - fostering competition and encouraging innovation. By including provisions that made the ANDA available to all generic drugs (not just those for pre-1962 drugs) and by extending patent protection for innovator drugs, the drafters of the Hatch-Waxman Act hoped to achieve balance between these goals.<sup>61</sup>

1.

### The Abbreviated New Drug Application (ANDA)

The first major change under the Hatch-Waxman Act was the extension of the Abbreviated New Drug Application process to *all* generics so as to promote the development of generic versions of more innovator

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<sup>60</sup>*Id.* at 15.

<sup>61</sup>See Henry Grabowski and John Vernon, *Longer Patents for Lower Imitation Barriers: The 1984 Drug Act*, 76 AM. ECON. REV. 195, 195 (1986).

drugs. As previously discussed, prior to the passage of the Hatch-Waxman Act, generic versions of post-1962 drugs still had to duplicate all of the safety and effectiveness tests conducted on the innovator drugs.<sup>62</sup> The Hatch-Waxman Act did away with this distinction between generic versions of pre-1962 drugs and generic versions of post-1962 drugs. Under Title I of the Hatch-Waxman Act, *all* generic manufacturers applying for an ANDA can rely on the safety and efficacy tests of the innovator manufacturer as long as they demonstrate that the generic version contains the same active ingredients as the innovator drug, that the generic is bioequivalent to the innovator drug, and that the product will be properly labeled.<sup>63</sup> Bioequivalence tests are much cheaper than the types of tests which are necessary in order to demonstrate safety and efficacy; therefore, this provision is extremely beneficial to generic manufacturers.<sup>64</sup> In order to receive FDA approval, the ANDA filer must also provide certification with respect to each of the innovator drug's patents listed in the FDA's Orange Book.<sup>65</sup> There are four different types of certification that a generic manufacturer can make to the FDA. A "Paragraph I" certification states that patent information for the innovator drug is not in the Orange Book.<sup>66</sup> A "Paragraph II" certification says that any patents for the innovator drug that are listed in the Orange Book have expired.<sup>67</sup> A "Paragraph III" certification provides the date that the innovator drug's patents will expire with the understanding that the ANDA will not receive final approval until such

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<sup>62</sup>See *supra* note 52 and accompanying text.

<sup>63</sup>See 21 U.S.C. § 355(j)(2)(A) (1999).

<sup>64</sup>See CBO STUDY, *supra* note 1.

<sup>65</sup>See 21 U.S.C. §355(j)(2)(A) (1999). As a part of the NDA filing process, innovator drug companies must submit a signed declaration listing the patent number and expiration date for all patents covering the drug or the method of use of the drug for which a claim of patent infringement could reasonably be claimed. See 21 U.S.C. §355(b)(1)(1999). The FDA then lists all of these patents in a document called the Orange Book (officially entitled the "Approved Drug Products with Therapeutic Equivalence Evaluations"). The FDA relies on the drug companies' representations as to the validity of the patents rather than making an independent determination as to the validity of the patents. See Elizabeth H. Dickinson, *Symposium: Striking the Right Balance Between Innovation and Drug Price Competition: Understanding the Hatch-Waxman Act: FDA's Role in Making Exclusivity Determinations*, 54 FOOD DRUG L.J. 195, 196 (1999).

<sup>66</sup>See *id.* §355(j)(2)(A)(vii)(I).

<sup>67</sup>See *id.* §355(j)(2)(A)(vii)(II).

date.<sup>68</sup> Finally, a “Paragraph IV” certification makes the claim that the innovator drug’s patents are invalid or will not be infringed by the applicant’s generic drug.<sup>69</sup> Generic manufacturers who file a Paragraph IV certification must notify the owner of each patent and the NDA holder for the innovator drug, as well as submit a detailed statement of the factual and legal basis of the opinion that the patent is not valid or will not be infringed.<sup>70</sup> Upon receiving a Paragraph IV certification, an innovator drug company has forty-five days in which to initiate a patent infringement suit against the ANDA applicant.<sup>71</sup> If the innovator does not bring suit, the FDA may begin the approval process. However, if the innovator does bring suit then the FDA automatically stays approval of the application until the earliest of a final determination that the patent has not been infringed, the expiration of the patent, or the passage of thirty months from the innovator’s receipt of notice of the Paragraph IV certification.<sup>72</sup> Because the FDA relies on the assertions of the innovator drug company with regard to the validity of its patents,<sup>73</sup> the Hatch-Waxman provides an additional incentive for manufacturers to challenge the validity of an innovator’s patents. Under the Act, the first ANDA filer to make a Paragraph IV certification with respect to a particular innovator drug receives a period of market exclusivity.<sup>74</sup> Subsequent generic versions of the innovator drug are not allowed to enter the market until 180 days from the earlier of the date of a court determination that the patent which is the subject of the Paragraph IV certification is either invalid or has not been infringed, or the date the FDA receives notice

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<sup>68</sup> See *id.* §355(j)(2)(A)(vii)(III).

<sup>69</sup> See *id.* §355(j)(2)(A)(vii)(IV).

<sup>70</sup> See *id.* §355(j)(2)(B)(i).

<sup>71</sup> See *id.* §355(j)(5)(B)(iii). Submission of a Paragraph IV certification to the FDA constitutes patent infringement for the purposes of federal court jurisdiction, thereby allowing the patent dispute to be resolved before the generic is marketed. See 35 U.S.C. §271(e)(2) (2001). See also Dickinson, *supra* note 63, at 198.

<sup>72</sup> See *id.* §355(j)(5)(B)(iii).

<sup>73</sup> See *supra* note 63.

<sup>74</sup> See 21 U.S.C. §355(j)(5)(B)(iv) (1999).

that the first ANDA filer has begun marketing the drug.<sup>75</sup> Thus, the ANDA provision balances the interests of pioneer drug manufacturers and generic drug manufacturers by providing the owner of the patent with what amounts to an automatic preliminary injunction of up to thirty months, while providing the generic an abbreviated approval process and a six-month exclusivity period. The thirty-month stay helps preserve the pioneers' incentives to innovate while the ANDA process and the market exclusivity provides generics with incentives to compete.

## 2.

### Patent Extensions

In addition to extending the ANDA process to all generic drugs, the Hatch-Waxman Act also includes important provisions relating to patents. The first significant patent provision in the Hatch-Waxman Act establishes patent-term extensions for innovator drugs in order to preserve the incentives to innovate.<sup>76</sup> Prior to the passage of Hatch-Waxman, an innovator drug had a patent term of seventeen years from the grant of the patent.<sup>77</sup> However, because innovator drugs had to go through the FDA approval process, the average length of time between when an innovator drug actually entered the market (and thus could profit from the drug) and when its patent expired was only nine years.<sup>78</sup> In an attempt to compensate innovator drug

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<sup>75</sup>See *id.*

<sup>76</sup>Patent extensions were not the only way that Congress attempted to encourage innovation. Congress created a minimum of five years of exclusivity even for those drugs which do not qualify for patent protection. During the first five years of market life for these drugs no ANDA can be submitted which refers to the unpatented drug. See 21 U.S.C. §355(j)(4)(D)(ii) (1999).

<sup>77</sup>See CBO STUDY, *supra* note 1.

<sup>78</sup>See *id.*

manufacturers for the loss of patent life that resulted from the post-1962 lengthier FDA approval process, the Hatch-Waxman Act provided innovator drug manufacturers with the ability to obtain a patent term extension.<sup>79</sup> In order to be considered for a patent extension, the innovator drug company must meet several requirements. First, the patent in question must not have expired before the application for extension is submitted.<sup>80</sup> Second, the patent in question must not previously have been extended.<sup>81</sup> Third, the owner of record of the patent must submit a proper application for extension.<sup>82</sup> Fourth, the drug covered by the patent must have been subject to a regulatory review period before its commercial marketing or use.<sup>83</sup> Fifth, the approval of the drug must have led to the first commercial marketing or use of the drug under applicable law.<sup>84</sup> Finally, an application containing details about the patent and the actions taken in order to obtain FDA approval must be submitted to the United States Patent and Trademark Office within sixty days of obtaining FDA approval for the drug.<sup>85</sup> In general, the Hatch-Waxman Act allows patents to be extended for a period equal to half the time the innovator drug spends in clinical tests after its patent is granted plus all of the time the FDA spends reviewing the NDA for the innovator drug.<sup>86</sup> However, the length of an extension is limited in several ways: 1) the patent may not be extended for more than five years, 2) the term allowed by the extension plus the remaining unexpired term on the patent may not exceed fourteen years, 3) the period covering activities prior to the issuance of the patent may not be counted, and 4) time during

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<sup>79</sup> See Klenfield, *supra* note 51, at 254.

<sup>80</sup> See 35 U.S.C. §156(a) (2001).

<sup>81</sup> See *id.*

<sup>82</sup> See *id.*

<sup>83</sup> See *id.*

<sup>84</sup> See *id.*

<sup>85</sup> See *id.* §156(d)(1).

<sup>86</sup> See *id.* §156(c),(g).

which the applicant failed to exercise due diligence cannot be counted.<sup>87</sup>As an additional limitation, only one patent for each innovator drug is eligible for an extension under the Hatch-Waxman Act.<sup>88</sup> The other major provision in the Hatch-Waxman Act relating to patents deals with defining activities constituting an act of patent infringement. Prior to 1984, any generic competitor attempting to enter the market had to worry about claims of patent infringement under the holding of *Roche Products v. Bolar Pharmaceuticals*. In *Bolar*, the court had held that the making, using, or selling of a patented invention was an act of patent infringement even if the only purpose of such activity was to obtain regulatory approval.<sup>89</sup>This holding meant, in essence, that generic competitors could not do anything towards obtaining FDA approval until a patent on an innovator drug expired. Thus, innovator drug companies had a *de facto* extension on their patents. The Hatch-Waxman Act changed this by declaring that making, using, or selling a patented invention solely for uses reasonably related to developing and submitting an ANDA to the FDA was not an act of infringement.<sup>90</sup>Thus, generics could make preparations to enter the market before the expiration of the innovator's patent. This provision reflected Congress's view that the preparation of an ANDA has no adverse economic impact on the patent holder's rights.<sup>91</sup>In addition, allowing ANDA preparation to commence before the pioneer's patent expires benefits competition by preventing the patent holder's exclusivity from extending beyond the expiration of patent rights. Thus, Congress hoped to strike an equilibrium between innovation and competition by balancing patent extensions with a provision that basically enabled generic drug companies to enter the market the day after the innovator's patent expired.

Despite overturning *Bolar*, the Hatch-Waxman Act did place one limit on the type of activities during the

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<sup>87</sup>See *id.*

<sup>88</sup>See *id.* §156(c)(4).

<sup>89</sup>See *Roche Prods. v. Bolar Pharm.*, 733 F.2d 858 (Fed. Cir. 1984).

<sup>90</sup>See 35 U.S.C. §271(e) (2001).

<sup>91</sup>See H.R. REP. NO. 98-857(I), *supra* note 48, at 46.

application process that would not constitute patent infringement. Under the statute, it is still an act of infringement to submit an ANDA for a drug under patent if the purpose of submitting the ANDA is to get approval of the ANDA with an effective date prior to the expiration of the patent.<sup>92</sup> This type of “constructive infringement” enables pioneer drug companies to bring patent infringement cases against those companies that file Paragraph IV certifications under the ANDA provisions. Ultimately, this provision serves as a balance to the 180-day exclusivity rule in the ANDA provisions - those generics who make Paragraph IV challenges are rewarded with the 180-day exclusivity period but pioneer drug companies still have the opportunity to defend their patent in court. Once again, policymakers provided generics an incentive to compete, but carefully tried not to destroy pioneers’ incentive to innovate in the process.

## C.

### **The Hatch-Waxman Balancing Act**

Congress intended the provisions of the Hatch-Waxman Act to strike a delicate balance between the needs of generic drug companies, the needs of innovator drug companies, and the overall needs of society. Congress included the ANDA provisions as a source of potential positive economic welfare gains to generic drug companies and to society as a whole. However, Congress recognized that these provisions might impose costs on innovator drug companies and ultimately on society. Thus, Congress also included the patent term extension provisions in order to try to alleviate these costs.

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<sup>92</sup>See *id.*

The first potential source of economic gain came from the abbreviated approval requirements for generic drugs. By allowing generic manufacturers to rely on the safety and efficacy tests of the innovator drug, the Act eliminated duplicative testing which had no valid scientific purpose.<sup>93</sup> The expectation was that the Act would reduce the cost of the approval process to generic drug manufacturers who would ultimately pass those savings on to consumers. The second potential source of economic gain came from the increased incentives for generic entry into the market. The existence of more generic competition was expected to lower prices for consumers and eliminate some of the deadweight loss to society that is typically associated with monopolies. The hope was that the statute would lead to beneficial transfers of wealth from producers to consumers.<sup>94</sup> Despite these potential economic gains, there was also the potential for economic loss. The existence of more vigorous competition in the pharmaceutical industry due to a larger generic market could potentially harm pioneer drug companies by lowering their market share or by forcing them to lower their prices.<sup>95</sup> As a result, pioneer drug companies would see a decrease in the expected returns on their research and development and would therefore have less incentive to pursue new innovations.<sup>96</sup> Given the harm that could result to consumers from decreased innovation in the pharmaceutical industry, the drafters of the Hatch-Waxman Act felt the need to balance the ANDA provisions that encouraged generic competition with provisions that would encourage pioneer innovation. The plan was for patent extension term provisions to maintain pioneer drug company profits enough to insure that the research and development of innovator drug companies would not suffer any major adverse effects.<sup>97</sup> Ultimately, the policymakers hoped that this would result in consumers having greater access to drugs that were both inexpensive and revolutionary.

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<sup>93</sup> See Grabowski, *supra* note 61, at 196.

<sup>94</sup> See *id.*

<sup>95</sup> See *id.*

<sup>96</sup> See *id.*

<sup>97</sup> See *id.* at 198.



D.

### **Antitrust Law and Intellectual Property Law Within the Context of the Hatch-Waxman Act**

Despite the fact that the Hatch-Waxman Act tries to embrace the policies underlying both the intellectual property laws and the antitrust laws, the two sets of laws still come into conflict under the statute's regulatory regime. This is particularly true in the context of patent litigation that arises under the Hatch-Waxman Act. First, since final FDA approval of a generic drug is delayed for up to thirty months if there is ongoing patent litigation, some innovator drug companies file frivolous patent infringement cases against potential generic entrants as a means of extending their market exclusivity. With these types of frivolous lawsuits, the policies underlying the intellectual property laws and the antitrust laws come into direct conflict with neither policy ultimately being furthered.<sup>98</sup> This is because the automatic thirty-month stay that is intended to counter any negative impacts on innovation winds up preventing a potential competitor from entering the market.

An even larger anticompetitive problem arises if the litigating parties do not pursue these patent infringement cases to their conclusion in the court system, but rather choose to settle their cases out of court. Although settlements often benefit both the private parties involved in a litigation and society as a whole, they can also raise significant antitrust concerns by eliminating or reducing competition.<sup>99</sup> The reduction in competition caused by these settlements may destroy some of the incentives that drug companies have for developing new, innovative products.<sup>100</sup> Thus, patent settlements may destroy the delicate balance between

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<sup>98</sup> See, e.g., *Hangards v. Ethicon*, 601 F.2d 986, 993 (9<sup>th</sup> Cir. 1979) (noting that “[p]atentees must be permitted to test the validity of their patents in court through actions against alleged infringers. . . . On the other hand, infringement actions initiated and conducted in bad faith contribute nothing to the furtherance of the policies of either the patent law or the antitrust law.”).

<sup>99</sup> See discussion *infra* Part IV.

<sup>100</sup> See *supra* note 39 and accompanying text.

innovation and competition that the drafters of the Hatch-Waxman Act hoped to create. The question for policymakers, then, becomes how to restore that equilibrium between encouraging innovation and fostering competition.

## IV.

### Patent Settlements and the Drug Price Competition and Patent Restoration Act of 1984

#### A.

##### General Overview of the Benefits and Costs of Settlements

Traditionally, the legal system has encouraged the settlement of ongoing litigation because of the benefits that incur to parties involved in litigation as well as the benefits that incur to society as a whole.<sup>101</sup> For parties involved in litigation, settlements are beneficial in that they allow the parties to avoid many of the transaction costs associated with litigating a case to its full conclusion.<sup>102</sup> Settlements are also beneficial to parties involved in litigation because they reduce risks and uncertainty.<sup>103</sup> Society benefits from settlements because they decrease court costs and reduce congestion within the judicial system.<sup>104</sup> Both the parties

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<sup>101</sup> See, e.g., *McDermott, Inc. v. AmClyde*, 511 U.S. 202, 215 (1994) (noting that “public policy wisely encourages settlement . . .”).

<sup>102</sup> Carl Shapiro, *Antitrust Limits to Patent Settlements*, May 1, 2001, available at <http://www.law.berkeley.edu/institutes/bclt/pubs/wp/501.pdf>.

<sup>103</sup> See *id.*

<sup>104</sup> See *id.*

involved in litigation and society benefit from quick resolution of the issues.<sup>105</sup> The legal system's preference for settlement is no different in the patent litigation context.<sup>106</sup> In addition to saving time and money and to reducing risk, patent settlements may provide added benefits if they clarify intellectual property rights and foster competition. Such benefits arise if a settlement allows the potential new entrant to bring their product to market sooner than expected or to bring it to market at all.<sup>107</sup> Settlements of a patent infringement case may also provide pro-competitive benefits if the terms of the agreement are such that the firms combine their intellectual property to introduce a new product that would not otherwise exist.<sup>108</sup> Finally, patent settlements, depending on their terms, may enable the settling parties to compete more effectively with other firms in the market.

Despite the preferential status given to settlements within the legal system, settlements are not always without their costs. All settlements, whether related to the resolution of patent disputes or not, may potentially harm society if they prevent resolution of a legal issue that may be applicable beyond just the case at hand.<sup>109</sup> The costs of patent settlements, in particular, can be quite high. This is because in addition to the private interests involved, there is also a public interest in limiting the grant of patent monopolies to "novel and useful inventions."<sup>110</sup> Within the patent arena, settlement without resolution of the legal issue can be quite problematic since patent infringement suits often acts as a check on the patent process by revealing

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<sup>105</sup> See *id.*

<sup>106</sup> See, e.g., *ARCO Corp. v. Allied Witan Co.*, 531 F.2d 1368, 1372 (6<sup>th</sup> Cir. 1976) (noting that "[p]ublic policy strongly favors settlement of disputes without litigation. Settlement is of particular value in patent litigation, the nature of which is inordinately complex and time-consuming.").

<sup>107</sup> See Thomas B. Leary, Commissioner, Federal Trade Commission, Antitrust Issues in Settlement of Pharmaceutical Patent Disputes, Remarks at the Sixth Annual Health Care Antitrust Forum, Northwestern University School of Law (Nov. 3, 2000), available at <http://www.ftc.gov/speeches/leary/learypharma.htm>.

<sup>108</sup> See Balto, *supra* note 5, at 328.

<sup>109</sup> See Shapiro, *supra* note 102.

<sup>110</sup> See Harry M. Reasoner and Scott J. Atlas, *Innovative Relief and Class Action Issues in Government and Private Actions: The Settlement of Litigation as a Ground for Antitrust Liability*, 50 ANTITRUST L.J. 115, 115 (1981).

information that would have kept the Patent and Trademark Office from issuing a patent had the information been disclosed.<sup>111</sup> Thus, settlements may impose costs on society by allowing inventions that are not worthy of patent protection to maintain their government-sanctioned monopoly.<sup>112</sup> Patent settlements may also impose costs on society if they foster collusion and restrict competition among parties.<sup>113</sup> There are numerous ways in which a patent settlement can be structured so as to reduce competition between the parties. For example, a patent holder may eliminate a potential competitor by using a settlement as an opportunity to purchase the firm challenging its patent.<sup>114</sup> A patent holder might also be able to eliminate a potential competitor by negotiating a settlement in which the patent challenger is paid in exchange for an agreement not to enter the market.<sup>115</sup> Even if a settlement does not entirely eliminate a potential competitor, competition can still be harmed if the two parties enter an agreement whereby they split up the market in some manner such that they both participate in the market but do not directly compete.<sup>116</sup> Finally, a challenger might agree to pay royalties to the patent holder in conjunction with a future fixed payment from the patent holder.<sup>117</sup>

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<sup>111</sup>See AREEDA, *supra* note 13, at 444.

<sup>112</sup>See *id.*

<sup>113</sup>See *id.*

<sup>114</sup>See *id.* In such cases, the patent holder would likely induce the sale by setting the purchase price so as to split the gains from decreased competition between the patent holder and the challenger.

<sup>115</sup>See *id.*

<sup>116</sup>See *id.*

<sup>117</sup>See *id.*

## B.

### Patent Settlements Within the Context of the Pharmaceutical Industry

In the pharmaceutical industry, the anticompetitive problems that arise out of patent settlements are played off against the special regulatory framework of the Hatch-Waxman Act. Patent settlements in the pharmaceutical context can be used as a pretext for paying off generic manufacturers in order to delay or prevent their entry into the market.<sup>118</sup> The entry of a generic product into the market will cause the profits of an innovator drug to decrease dramatically.<sup>119</sup> Because this drop in the innovator drug company's monopoly profits will be much larger than the anticipated profits of the generic manufacturer in a competitive market, there are incentives for the innovator and the generic to cooperate.<sup>120</sup> If the generic manufacturer is unsure about its chances of winning the case, it has an incentive to settle and delay entry into the market until the case is concluded since potential damages for infringement, measured in terms of the innovator's lost monopoly profits, would greatly exceed the profits that the entrant would make in a competitive market.<sup>121</sup> The innovator has an incentive to settle, even if it is confident that it can win, because the generic manufacturer most likely would not be able to pay damages if it lost the suit, meaning that the innovator would not be able to recover lost profits.<sup>122</sup> If the innovator is not confident about its chances, it has even more incentive to settle in order to maintain its monopoly over the market and it is likely to be willing to

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<sup>118</sup>See Lara J. Glasgow, *Stretching the Limits of Intellectual Property Rights: Has the Pharmaceutical Industry Gone Too Far?*, 41 IDEA: J.L. & TECH. 227 (2001).

<sup>119</sup>See Leary, *supra* note 107.

<sup>120</sup>See *id.*

<sup>121</sup>See *id.*

<sup>122</sup>See *id.*

share part of its monopoly rents in order to do so.<sup>123</sup> In these circumstances, the generic manufacturer still has incentive to settle assuming that the innovator pays the generic as much, if not more, money than the generic would receive by entering the competitive market.<sup>124</sup> Delayed entry of the generic drug that is the subject of the suit is not the only potential problem with these settlements. These settlements also raise problems because they sometimes involve restrictions on non-infringing drugs in addition to restrictions on the drug at issue in the case.<sup>125</sup> In the Hatch-Waxman context, patent litigation settlements may prove even more problematic because they usually affect not only the involved parties but also non-party manufacturers. Since the Hatch-Waxman Act does not allow any other generic to enter the market until the first generic has been on the market for 180 days, innovator drug companies can use settlements to prolong their market exclusivity.<sup>126</sup> There are several ways in which an innovator drug company can use a settlement to prolong its market exclusivity. First, the innovator and the generic can enter into a settlement that results in a judgment in favor of the validity of the patent.<sup>127</sup> The effect of this is to prevent the generic from obtaining FDA approval and thus from marketing its version of the drug until the patent runs out, meaning that the 180-day exclusivity period does not begin until the patent expires.<sup>128</sup> Second, if the innovator is not likely to prevail in court, the generic might agree to stay out of the market for money or lucrative licenses on other products.<sup>129</sup> Third, even if the innovator is in a strong position, the two parties might enter into a

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<sup>123</sup> See Sheila F. Anthony, Commissioner, Federal Trade Commission, Riddles and Lessons from the Prescription Drug Wars: Antitrust Implications of Certain Types of Agreements Involving Intellectual Property, Presented Before the Attendees of the ABA “Antitrust and Intellectual Property: The Crossroads” Program (June 1, 2000), *available at* <http://www/ftc/gov/speeches/Anthony/sfip000601.htm>.

<sup>124</sup> See *id.*

<sup>125</sup> See Glasgow, *supra* note 118.

<sup>126</sup> See Balto, *supra* note 5, at 331.

<sup>127</sup> See *id.*

<sup>128</sup> See *id.*

<sup>129</sup> See *id.*

partial settlement that provides the generic with incentives not to enter the market until after the patent expires (for example, payments or lucrative licenses for other products).<sup>130</sup> Finally, the settlement might contain provisions that prevent waivers of the 180-day exclusivity period.<sup>131</sup> Thus, patent settlements in the pharmaceutical industry pose numerous anticompetitive problems for the antitrust authorities.

## C.

### Patent Litigation Settlements and The Antitrust Laws

The legal precedents with regard to antitrust challenges to patent settlement cases indicate that patent settlements are not per se illegal, but rather require a fact-specific inquiry. In a leading United States Supreme Court case on settlements, *Standard Oil Co. v. United States*, the Court held that “where there are legitimately conflicting [patent] claims or threatened interferences, a settlement by agreement, rather than by litigation, is not precluded by the [Sherman] Act.”<sup>132</sup> However, thirty years later, in *United States v. Singer Manufacturing Co.*, the United States Supreme Court, specifically addressing patent settlements, rejected the District Court’s conclusion that the purpose of the agreement between the two parties involved in the case had been primarily the settlement a dispute.<sup>133</sup> Instead, the Court concluded that the settlement agreement between the parties had been part of a scheme to restrain trade and exclude foreign competition.<sup>134</sup> In

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<sup>130</sup> See *id.*

<sup>131</sup> See *id.*

<sup>132</sup> *Standard Oil Co. v. U.S.*, 283 U.S. 163, 171 (1931).

<sup>133</sup> See *U.S. v. Singer Mfg Co.*, 374 U.S. 174, 192 (1963).

<sup>134</sup> See *id.* at 194-95.

reaching this conclusion, the Court made clear that it is “not the mere act of settlement but the intent of the parties in entering into that settlement and their action pursuant thereto that, in law, constitute [an antitrust] violation.”<sup>135</sup> In a concurring opinion, Justice Byron White noted that “the settlement of an interference in which the only interests at stake are those of the adversaries... may well be consistent with the general policy favoring settlement of litigation.”<sup>136</sup> However, he went on to note that:

[T]he present case involves a less innocuous setting... [in] which the parties have subordinated to their private ends—the public interest in granting patent monopolies only when the progress of the useful arts and of science will be furthered because as consideration for its grant the public is given a novel and useful invention.<sup>137</sup>

Thus, despite the fact that patent settlements are not per se illegal, it seems that absent any pro-competitive justifications, patent settlements that negatively affect competition are likely to be illegal. When adding considerations of the costs and benefits of patent settlements to the delicate balancing act between intellectual property rights and antitrust, the antitrust authorities are presented with a complex framework of conflicting objectives. All of these objectives must be considered when analyzing patent infringement settlements in the Hatch-Waxman context and when looking for ways to solve the problems that they create.

## V.

### Specific Patent Settlement Cases in the Pharmaceutical Industry

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<sup>135</sup>Duplan Corp. v. Deering Milliken, Inc., 540 F.2d 1215, 1221 (4<sup>th</sup> Cir. 1976) (discussing *Standard Oil Co. v. U.S.*, 283 U.S. 163 (1931)).

<sup>136</sup>*Singer Mfg.*, 374 U.S. at 199.



Three cases filed by the Federal Trade Commission against brand name drug manufacturers and generic drug manufacturers provide examples of the types of anticompetitive concerns that arise in the context of patent settlements in the pharmaceutical industry. The first of these cases involved a settlement between Abbott Laboratories (“Abbott”) and Geneva Pharmaceuticals, Inc. (“Geneva”) related to the marketing of a generic version of the drug Hytrin. The second case involved a settlement between Hoechst Marion Roussel, Inc. (“Hoechst MRI”) and Andrx Corporation (“Andrx”) over the marketing of a generic version of the drug Cardizem CD. The final case involved a settlement between Schering-Plough Corporation (“Schering”) and Upsher-Smith Laboratories (“Upsher”) as well as a settlement between Schering-Plough Corporation and American Home Products Corporation (“AHP”), both of which related to generic versions of K-Dur 20.

## A.

### Abbot Laboratories and Geneva Pharmaceuticals

Abbott Laboratories began marketing the tablet form of Hytrin, the pioneer drug in the United States containing terazosin hydrochloride (“terozosin HCL”), in 1987.<sup>138</sup> Hytrin has been one of Abbott’s most important products because of its profitability. In 1998 alone, Abbott’s sales of Hytrin in the United States were \$542 million.<sup>139</sup> During the first six months of 1999, Abbott reported \$292 million in United States sales of Hytrin, twenty percent of the net sales of Abbott’s United States pharmaceutical products division.<sup>140</sup>

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<sup>138</sup> See Complaint ¶ 10, 11, 14, In the Matter of Abbott Labs. And Geneva Pharm., (May 22, 2000) (FTC Dkt. No. C-3945), available at <http://www.ftc.gov/os/2000/05/abbottgenevacomp.htm>. Terazosin hydrochloride is a compound used to treat benign prostatic hyperplasia and hypertension. Abbott introduced a capsule form of Hytrin in 1995. See *id.*

<sup>139</sup> See *id.*

<sup>140</sup> See *id.*

Geneva was the first manufacturer to file an ANDA under the Hatch-Waxman Act for a generic version of terazosin HCL.<sup>141</sup> It filed an ANDA for a tablet version in January 1993 and for a capsule version in December 1995.<sup>142</sup> Shortly thereafter, in early 1996, Abbott notified the FDA of a new patent that it had obtained related to Hytrin, prompting the FDA to list the new patent in the FDA Orange Book.<sup>143</sup> Then, in April 1996, Geneva filed a Paragraph IV certification with the FDA under the ANDA provisions of the Hatch Waxman-Act.<sup>144</sup> In its certification, Geneva claimed that neither its tablet version nor its capsule version infringed on any of Abbott's Hytrin patents, including the newly listed patent.<sup>145</sup> Keeping with the provisions of the Hatch-Waxman Act, Geneva then notified Abbott of the Paragraph IV certification.<sup>146</sup> In response to Geneva's Paragraph IV certification, Abbott filed a patent infringement suit against Geneva related to the tablet product in the Northern District of Illinois on June 4, 1996.<sup>147</sup> This lawsuit triggered the Hatch-Waxman Act thirty-month stay for the tablet version, meaning that Geneva could not bring its generic tablet version to market until December 1998.<sup>148</sup> Abbott failed, however, to file a claim related to the capsule product within the forty-five day period mandated by the Hatch-Waxman Act.<sup>149</sup> Thus, FDA review of the ANDA for the capsule version continued and on March 30, 1998, the FDA granted Geneva final approval to market generic terazosin HCL capsules.<sup>150</sup> Because Geneva was the first manufacturer to submit Paragraph

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<sup>141</sup> See *id.* ¶ 16.

<sup>142</sup> See *id.*

<sup>143</sup> See *id.* ¶ 17.

<sup>144</sup> See *id.*

<sup>145</sup> See *id.*

<sup>146</sup> See *id.*

<sup>147</sup> See *id.* ¶ 18.

<sup>148</sup> See *id.* ¶ 19.

<sup>149</sup> See *id.*

<sup>150</sup> See *id.* ¶ 22.

IV certification, it was entitled to the Hatch-Waxman Act's 180-day exclusivity period for both its capsule version and its tablet version.<sup>151</sup> Upon receiving final FDA approval on March 30, Geneva told Abbott that it would begin marketing its generic version of terazosin HCL capsules unless paid by Abbott.<sup>152</sup> According to estimates made by Abbott, entry of Geneva's generic capsules on April 1, 1998 would have eliminated over \$185 million in Hytrin sales in a six-month period.<sup>153</sup> Wanting to keep generic versions of Hytrin off the market until February 2000, and estimating that Geneva's revenues for launching a generic would be one to one-and-a-half million dollars, Abbott negotiated an agreement with Geneva whereby Abbott would pay a premium over Geneva's estimated revenues to prevent Geneva from entering the market.<sup>154</sup> More specifically, under the April 1, 1998 agreement, Geneva would not enter the market with *either* a generic terazosin HCL capsule or tablet product until the earlier of 1) the final resolution of the tablet patent infringement case, including review all the way up to the United States Supreme Court, or 2) entry of another generic terazosin HCL product onto the market.<sup>155</sup> Geneva also would not transfer, assign, or relinquish its right to the 180-day exclusivity period to another drug manufacturer.<sup>156</sup> In return, Abbott agreed to pay Geneva \$4.5 million a month in non-refundable payments until there was a district court judgment in the patent infringement litigation.<sup>157</sup> If the district court determined that Geneva's tablet product did not infringe on Abbott's patents, then Abbott would pay 4.5 million a month into an escrow fund until the final resolution of the litigation, with whomever ultimately prevailed in the litigation receiving the money from the escrow fund.<sup>158</sup>

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<sup>151</sup> See *id.* ¶23.

<sup>152</sup> See *id.* ¶24.

<sup>153</sup> See *id.*

<sup>154</sup> See *id.* ¶24, 25.

<sup>155</sup> See *id.* ¶26

<sup>156</sup> See *id.*

<sup>157</sup> See *id.* ¶27.

<sup>158</sup> See *id.*

On September 1, 1998, the district court granted Geneva's motion for summary judgment, invalidating Abbott's patent under the on-sale provision of 35 U.S.C. §102(b).<sup>159</sup> The court was unaware of the agreement between Abbott and Geneva,<sup>160</sup> however, Geneva kept to the agreement and did not enter into the market with either its generic capsules or tablets.<sup>161</sup> The United States Court of Appeals for the Federal Circuit affirmed the summary judgment on July 1, 1999.<sup>162</sup> By August 1999, the parties became aware that the FTC was investigating their agreement and decided to cancel it.<sup>163</sup> On August 13, 1999, Geneva entered the terazosin HCL market with its generic capsule product.<sup>164</sup> The United States Supreme Court denied certiorari on January 10, 2000.<sup>165</sup> In May 2000, the Federal Trade Commission brought an enforcement action against Abbott and Geneva, alleging that the two drug manufacturers had engaged in conduct that violated Section 5 of the Federal Trade Commission Act, 15 U.S.C. §45.<sup>166</sup> Specifically, the FTC claimed: 1) that the agreement between the parties was an unreasonable restraint of trade, 2) that the parties had acted with the specific intent that Abbott monopolize the market and had engaged in acts to further the conspiracy to monopolize, 3) that Abbott had exercised its monopoly power in the relevant market, and 4) that the parties' acts were unfair methods of competition.<sup>167</sup> The FTC maintained that the effect of these antitrust violations was to deprive consumers of the benefit of new competition from Geneva, thus forcing them to buy a more expensive

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<sup>159</sup> See *id.* ¶31.

<sup>160</sup> See *id.* ¶28.

<sup>161</sup> See *id.* ¶32.

<sup>162</sup> See *id.* ¶33.

<sup>163</sup> See *id.*

<sup>164</sup> See *id.*

<sup>165</sup> See *id.*

<sup>166</sup> See *id.* ¶40.

<sup>167</sup> See *id.* ¶40-43.

brand-name product.<sup>168</sup> Because the settlement also barred Geneva from relinquishing its 180-day exclusivity period, the violations also had the effect of preventing any other generic from entering the market despite the fact that as of February 1999 at least one other generic terazosin HCL had satisfied the FDA's approval requirements.<sup>169</sup> As a result of the investigation, Abbott and Geneva entered into a consent order with the FTC. In general, the consent order barred restrictions on giving up the Hatch-Waxman 180-day exclusivity period and on entering the market with a non-infringing product.<sup>170</sup> The consent order also required court approval for any payments made to generics in exchange for an agreement to stay off the market when such an agreement is made in the context of interim settlement of patent litigation.<sup>171</sup> In addition to seeking court approval, the parties were also required to provide the FTC with notice of any payment so that the Commission can present its views to the court.<sup>172</sup> The order also required Abbott and Geneva to give the FTC written notice thirty days before entering into any other settlement in any other context.<sup>173</sup> Finally, the consent order required Geneva to waive its right to the 180-day exclusivity period for its generic tablet product.<sup>174</sup> The consent order in the Abbott/Geneva case was the first resolution of a challenge by antitrust enforcers to a private settlement made in the context of the Hatch-Waxman Act's provisions. This consent order was issued the same day the FTC issued a complaint against two other pharmaceutical companies, Hoechst Marion Russell, Inc. and Andrx Corporation, alleging similar antitrust violations. However, despite

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<sup>168</sup> See *id.* ¶35.

<sup>169</sup> See *id.* ¶38.

<sup>170</sup> Statement of Chairman Robert Pitofsky and Commissioners Sheila F. Anthony, Mozelle W. Thompson, Orson Swindle, and Thomas B. Leary, Abbott Laboratories and Geneva Pharmaceuticals, Inc., Docket Nos. C-3945 and C-3946, *available at* <http://www.ftc.gov/os/2000/abbottgenevastatement.htm>.

<sup>171</sup> See *id.*

<sup>172</sup> See *id.*

<sup>173</sup> See *id.*

<sup>174</sup> See *id.*

the similarities between the cases, the FTC did not advocate a per se rule against such settlements. Rather, the Commission advocated a fact-specific inquiry into whether there were any pro-competitive justifications for such an agreement.<sup>175</sup> The FTC put pharmaceutical companies on notice that such arrangements have the potential to cause serious anticompetitive problems and would be closely scrutinized.<sup>176</sup> The FTC also put companies on notice that in the future the Commission might consider pursuing the full range of remedies available under the antitrust laws, including disgorgement of profits.<sup>177</sup>

## B.

### Hoechst Marion Roussel, Inc. and Andrx Corporation

The same day the FTC filed the consent order in the Abbott/Geneva case, the Commission issued an administrative complaint against two other pharmaceutical companies, Hoechst Marion Roussel, Inc. and Andrx Corporation, alleging concerns similar to those expressed in the Abbott/Geneva case. The case involving Hoechst MRI and Andrx revolved around the market for once-a-day diltiazem, a type of calcium channel blocker for which there is no acceptable substitute.<sup>178</sup> Hoechst MRI was the manufacturer of the brand-name drug Cardizem CD, a cardiovascular drug used to treat hypertension and angina.<sup>179</sup> According to the FTC, Cardizem CD accounted for over seventy percent of the total sales of once-a-day diltiazem and thus gave

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<sup>175</sup> See *id.* (emphasizing that “[the FTC] recognize[s] that there may be market settings in which similar but less restrictive arrangements could be justified, and each case must be examined with respect to its particular facts.”)

<sup>176</sup> See *id.*

<sup>177</sup> See *id.*

<sup>178</sup> See Complaint ¶ 12, In the Matter of Hoechst Marion Roussel, Inc., Carderm Capital L.P., and Andrx Corp. (Mar. 16, 2000) (FTC Dkt No. 9293) [hereinafter Hoechst MRI Complaint], *available at* <http://www.ftc.gov/os/2000/03/hoechstandr-complaint.htm>.

<sup>179</sup> See *id.* ¶1.

Hoechst MRI monopoly power in the United States over the once-a-day diltiazem market.<sup>180</sup>Hoechst MRI estimated that a generic version of Cardizem CD, sold at seventy percent of Cardizem CD's price, would capture around forty percent of Cardizem CD's sales within a year.<sup>181</sup> Andrx filed the first ANDA under the Hatch-Waxman Act for a generic version of Cardizem CD in September 1995.<sup>182</sup>In December 1995, Andrx notified Hoechst MRI of its Paragraph IV certification and became entitled to the 180-day exclusivity period under the Hatch-Waxman Act.<sup>183</sup>Hoechst MRI filed a patent infringement suit against Andrx in the Southern District of Florida on January 31, 1996.<sup>184</sup>Since this was within the forty-five day filing period prescribed by the Hatch-Waxman Act, the suit triggered a thirty-month stay on sales of Andrx's generic version until July 1998.<sup>185</sup> In addition to Andrx, two other companies submitted ANDA's for generic versions of Cardizem CD. Purepac Pharmaceutical Co. filed an ANDA with the FDA in January 1997.<sup>186</sup>In response, Hoechst MRI filed a patent infringement case against Purepac in the Southern District of New Jersey, triggering a thirty-month stay until July 1999.<sup>187</sup>Biovail Corporation International filed the third ANDA for generic once-a-day diltiazem on June 19, 1997. In August 1997, Hoechst MRI offered to pay Biovail money to complete the testing and FDA approval process for a new Probucol indication.<sup>188</sup>At the time, Hoechst MRI held the NDA for Probucol but was neither marketing nor selling the drug.<sup>189</sup>Hoechst

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<sup>180</sup>See *id.* ¶14.

<sup>181</sup>See *id.* ¶30.

<sup>182</sup>See *id.* ¶17.

<sup>183</sup>See *id.*

<sup>184</sup>See *id.* ¶18.

<sup>185</sup>See *id.*

<sup>186</sup>See *id.* ¶19.

<sup>187</sup>See *id.*

<sup>188</sup>See *id.* ¶21.

<sup>189</sup>See *id.*

MRI's offer was contingent on an agreement by Biovail not to enter into the once-a-day diltiazem market with a generic version of Carizem CD until July 1999.<sup>190</sup> Biovail rejected Hoechst MRI's proposal, however, Hoechst MRI still did not sue Biovail for patent infringement with regard to the ANDA for a generic version of Cardizem CD.<sup>191</sup> In late July of 1997, Hoechst MRI and Andrx began discussing a possible settlement to their patent litigation.<sup>192</sup> Finally, on September 24, 1997, nine months before the 30-month stay was set to expire, Hoechst MRI and Andrx entered into an agreement that did not settle the patent infringement suit but did delay Andrx's entry into the market.<sup>193</sup> Andrx agreed not to enter the market until the earliest of 1) entry of final judgment in the patent infringement case, 2) Andrx obtaining a license from Hoechst MRI, or 3) Hoechst MRI providing notice to Andrx of an intent to license a third party or to sell its own generic version of Cardizem CD.<sup>194</sup> In addition, Andrx agreed not to sell any non-infringing bioequivalent or generic version of Cardizem, and not to withdraw its ANDA or give up its 180-day exclusivity period until entry of the final judgment in the patent infringement case.<sup>195</sup> In return, Hoechst MRI agreed to begin paying Andrx ten million dollars per quarter once Andrx obtained final FDA approval of its ANDA.<sup>196</sup> Hoechst was to continue to making such payments throughout the time period referred to above.<sup>197</sup> Were Hoechst MRI to lose the patent litigation suit, the agreement also called for Hoechst MRI to pay Andrx an additional sixty million dollars per year for that same time period.<sup>198</sup> The agreement also included a provision whereby Andrx

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<sup>190</sup> See *id.*

<sup>191</sup> See *id.*

<sup>192</sup> See *id.* ¶ 22.

<sup>193</sup> See *id.* ¶ 23.

<sup>194</sup> See *id.*

<sup>195</sup> See *id.*

<sup>196</sup> See *id.* ¶ 24.

<sup>197</sup> See *id.*

<sup>198</sup> See *id.*



had the option to license Cardizem CD beginning January 9, 2000 with the amount of royalties to be set based on the ultimate outcome of the patent infringement case.<sup>199</sup> On July 9, 1998 Andrx received final FDA approval for its ANDA, but upheld its agreement with Hoechst MRI and did not begin marketing its generic version of Cardizem CD.<sup>200</sup> In return, Hoechst MRI began its quarterly payments to Andrx.<sup>201</sup> Subsequently, Andrx filed a supplemental ANDA for a modified version of its generic Cardizem CD with the FDA and gave Hoechst MRI notice of Paragraph IV certification for the supplemental ANDA.<sup>202</sup> In June of 1999, the FDA approved Andrx's supplemental ANDA, and Andrx and Hoechst MRI entered into a new agreement that did away with the first agreement.<sup>203</sup> This new agreement allowed Andrx to begin marketing its generic version of Cardizem CD so Andrx entered the market with its generic version on June 23, 1999.<sup>204</sup> On March 16, 2000, the FTC filed a complaint against Hoechst MRI and Andrx alleging various violations of Section 5 of the Federal Trade Commission Act. Although the agreement at issue had already been terminated, the FTC proceeded with its case to prevent the recurrence of similar agreements.<sup>205</sup> The FTC alleged that 1) the agreement between Hoechst MRI and Andrx constituted an unreasonable restraint on trade, 2) Hoechst MRI had attempted to monopolize the once-a-day diltiazem market through both its agreement with Andrx and its attempt to reach a similar agreement with Biovail, 3) Hoechst MRI and Andrx had conspired to monopolize the relevant market, and 4) the two companies had engaged in actions which constituted unfair

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<sup>199</sup> See *id.* ¶25.

<sup>200</sup> See *id.* ¶27.

<sup>201</sup> See *id.*

<sup>202</sup> See *id.* ¶28.

<sup>203</sup> See *id.*

<sup>204</sup> See *id.*

<sup>205</sup> See Analysis to Aid Public Comment at 4, In the Matter of Hoechst Marion Roussel, Inc., Carderm Capital L.P., and Andrx Corp. (Apr. 2, 2001) (FTC Dkt. No. 9293) [hereinafter Hoechst MRI Analysis], *available at* <http://www.ftc.gov/os/2001/04/hoechstanalysis.pdf>.

methods of competition.<sup>206</sup> In April 2001, the FTC announced a consent order with Hoechst MRI and Andrx.<sup>207</sup> The FTC's consent order barred agreements with restrictions on 1) giving up the 180-day exclusivity period of Hatch-Waxman and 2) entering the market with a non-infringing product.<sup>208</sup> The consent order also required court approval of interim settlements whereby generic manufacturers temporarily delay market entry in return for payments from the brand name manufacturer, and required that notice of such agreements be given to the FTC so that the Commission could make comments to the court.<sup>209</sup> Finally, the order required Hoechst MRI and Andrx to give the FTC thirty days written notice before entering into similar agreements in other situations.<sup>210</sup> As with the Abbott/Geneva case, the FTC did not advocate a per se rule against patent settlements, but rather utilized a fact-specific approach that asked whether the arrangement had any pro-competitive justifications which outweighed the anticompetitive effects.

## C.

### **Schering-Plough Corporation, Upsher-Smith Laboratories, and American Home Products Corporation**

The third FTC case involving patent settlements within the pharmaceutical industry differs slightly from the first two in that it involves two separate agreements and three different pharmaceutical companies. At issue

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<sup>206</sup> See Hoechst MRI Complaint, *supra* note 178, at ¶¶ 36-39.

<sup>207</sup> See Hoechst MRI Analysis, *supra* note 205, at 5.

<sup>208</sup> See *id.*

<sup>209</sup> See *id.*

<sup>210</sup> See *id.*

in the case involving Schering, Upsher, and AHP, was K-Dur 20, a prescription drug sold by Schering.<sup>211</sup> K-Dur 20 is a twenty milliequivalent extended release potassium chloride supplement that is sold in both tablet and capsule forms.<sup>212</sup> While potassium chloride itself is not patentable, Schering held a formulation patent for K-Dur 20 related to the product's controlled release properties.<sup>213</sup> Schering had approximately sixty-nine percent of the sales in the potassium chloride supplement market and one hundred percent of the sales in the twenty milliequivalent extended release potassium chloride tablet and capsule markets.<sup>214</sup> There were no practical substitutes for potassium chloride supplements at that point, and while there were potassium chloride products other than K-Dur 20, those products had not restricted Schering's ability to price K-Dur 20.<sup>215</sup> At the time the FTC filed suit, there was an NDA pending for a new powder form of potassium chloride.<sup>216</sup> However, this new product had not yet been approved and probably would not have decreased Schering's market share anyway because of the advantages that tablet and capsules have over powders.<sup>217</sup> On August 6, 1995 Upsher-Smith filed an ANDA and Paragraph IV certification with the FDA for Klor Con M20.<sup>218</sup> The ANDA for Klor Con M20 was the first ANDA for a generic version of K-Dur 20 to be filed with the FDA.<sup>219</sup> Schering estimated that in the first year that K-Dur had generic competition, its sales would

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<sup>211</sup> See Complaint ¶1, In the Matter of Schering-Plough Corp., Upsher-Smith Labs., and American Home Prods. Corp. (Mar. 30, 2001) (FTC Dkt. No. 9297), *available at* <http://www.ftc.gov/os/2001/04/scheringpart3cmp.pdf>. K-Dur 20 is used to treat patients with insufficient levels of potassium. *See id.*

<sup>212</sup> *See id.* ¶22.

<sup>213</sup> *See id.* ¶33, 34.

<sup>214</sup> *See id.* ¶¶26, 27.

<sup>215</sup> *See id.* ¶¶23, 25.

<sup>216</sup> *See id.* ¶28.

<sup>217</sup> *See id.*

<sup>218</sup> *See id.* ¶38.

<sup>219</sup> *See id.*

be reduced by over \$30 million.<sup>220</sup>Therefore, Schering stood to see a substantial loss in profits if a generic version of K-Dur obtained FDA approval.

Upsher notified Schering of its Paragraph IV certification on November 3, 1995.<sup>221</sup>In December 1995, Schering sued Upsher-Smith in the District of New Jersey, thus triggering the thirty-month stay on final FDA approval mandated by the Hatch-Waxman Act.<sup>222</sup>In the first half of 1997, as the infringement case progressed, Upsher-Smith began to make preparations to introduce Klor Con M20 to the market upon expiration of the thirty-month stay in May 1998.<sup>223</sup>However, on June 17, 1997, right before the infringement case went to trial, Schering and Upsher-Smith agreed to settle the litigation.<sup>224</sup>In exchange for a promise by Upsher-Smith not to enter the market with either Klor Con M20 or any other generic version of K-Dur 20, regardless of whether that product infringed on Schering's patents, Schering promised to pay Upsher-Smith payments of sixty million dollars.<sup>225</sup>The settlement also included a provision whereby Schering received licenses to market five of Upsher-Smith's products.<sup>226</sup>Four of these products Schering never actually sold on the market.<sup>227</sup>At the time of the suit, Schering had no expectation of making additional sales of any of the five products.<sup>228</sup>Finally, under the settlement, both parties agreed to dismiss the infringement case without prejudice.<sup>229</sup>In November 1998, Upsher-the FDA gave Upsher-Smith final approval to sell Klor Con M20,

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<sup>220</sup>See *id.* ¶37.

<sup>221</sup>See *id.* ¶38.

<sup>222</sup>See *id.* ¶39.

<sup>223</sup>See *id.* ¶43.

<sup>224</sup>See *id.* ¶44.

<sup>225</sup>See *id.*

<sup>226</sup>See *id.*

<sup>227</sup>See *id.*

<sup>228</sup>See *id.* ¶44, 46.

<sup>229</sup>See *id.* ¶44.

however, Upsher-Smith upheld its end of the settlement and did not attempt to bring the generic to the market.<sup>230</sup> On December 12, 1995, ESI Lederle, Inc., a division of AHP [hereinafter collectively referred to as “AHP”], filed an ANDA with the FDA for a generic version of K-Dur 20 and notified Schering of the Paragraph IV certification.<sup>231</sup> Because AHP was the second ANDA filer, it planned to market its generic only after Upsher-Smith’s 180-day exclusivity period had ended.<sup>232</sup> Upon receiving notice of AHP’s ANDA and Paragraph IV certification, Schering filed a patent infringement case against AHP in the Eastern District of Pennsylvania in February 1996.<sup>233</sup> By January 1998, Schering and AHP had reached an agreement in principle to settle the infringement case.<sup>234</sup> On June 19, 1998, they formally executed the final settlement agreement.<sup>235</sup> Under the agreement, AHP agreed not to market more than one generic version of K-Dur 20 between January 2004 and September 2006, and not to participate in any bioequivalence studies until September 2006.<sup>236</sup> In return, Schering promised to pay AHP five million dollars with another ten million dollar payment to follow if AHP could prove that it would get FDA approval by June 30, 1999, and an additional payment of fifteen million dollars for licenses on two generics that AHP was developing.<sup>237</sup> The FTC alleged that the fifteen million dollars was not actually related to the value of the licensed products, but rather represented the amount that AHP wanted in order to settle the case.<sup>238</sup> On May 11, 1999, AHP received tentative approval from the FDA of its ANDA with final approval withheld until the conclusion of

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<sup>230</sup> See *id.* ¶49.

<sup>231</sup> See *id.* ¶51.

<sup>232</sup> See *id.* ¶52.

<sup>233</sup> See *id.* ¶53.

<sup>234</sup> See *id.* ¶54.

<sup>235</sup> See *id.* ¶58.

<sup>236</sup> See *id.* ¶55.

<sup>237</sup> See *id.* ¶55.

<sup>238</sup> See *id.* ¶57.

Upsher-Smith's 180-day exclusivity period.<sup>239</sup> On June 2, 1999, Andrx Corporation filed a third ANDA for a generic version of Schering's K-Dur 20, but at the time of the FTC's investigation, Schering had not sued Andrx for patent infringement.<sup>240</sup> Like AHP, Andrx was unable to receive final approval from the FDA to market its generic until Upsher-Smith's 180-day exclusivity period expired. The FTC did not take action against Andrx in this case.

The FTC filed a complaint against Schering, Upsher-Smith, and AHP on March 30, 2001. The complaint alleged that the conduct of these three companies violated Section 5 of the Federal Trade Commission Act. Specifically, the FTC claimed: 1) that Schering and Upsher-Smith's agreement was an unreasonable restraint on commerce and thus an unfair method of competition, 2) that Schering and AHP's agreement was also an unreasonable restraint on commerce and thus an unfair method of competition, 3) that Schering unlawfully tried to preserve its monopoly power, and 4) that Schering, Upsher-Smith, and AHP had engaged in a conspiracy to monopolize.<sup>241</sup> The FTC's claims against Schering and Upsher-Smith are still pending resolution, however, the Commission has announced a proposed consent order with AHP.<sup>242</sup> The order prohibits agreements in which the NDA holder gives the ANDA filer something of value in exchange for a promise not to enter the market for a certain period of time as well as agreements in which the ANDA filer agrees not to enter the market with a non-infringing generic product.<sup>243</sup> These terms apply to AHP regardless of whether it is the ANDA filer or the NDA holder.<sup>244</sup> The proposed order does distinguish between what AHP could do as an ANDA first filer and what it could do as a subsequent filer in that as a first filer it cannot receive

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<sup>239</sup> See *id.* ¶60.

<sup>240</sup> See *id.* ¶61.

<sup>241</sup> See *id.* ¶68-71.

<sup>242</sup> See Agreement Containing Consent Order, In the Matter of Schering-Plough Corp., Upsher-Smith Labs., and American Home Prods. Corp. (Feb. 9, 2002) (FTC Dkt. No. 9297).

<sup>243</sup> See Schering Analysis, *supra* note 4, at 3.

<sup>244</sup> See *id.*

anything of value but as a subsequent filer it can get a delayed license to market the ANDA product from the NDA holder.<sup>245</sup> This distinction is made because as a subsequent filer, AHP would not be able to block entry by other potential competitors.<sup>246</sup>

## D.

### FTC Antitrust Concerns

Although there are often benefits to be gained from the settlement of ongoing litigation,<sup>247</sup> the settlements in each of these cases were challenged by the FTC because of the anticompetitive impact that each had on the product market in question. On the most basic level, the settlements were problematic because they were agreements between potential horizontal competitors that restricted competition by delaying the entry of a new product.<sup>248</sup> The restraints on competition were particularly harmful in these settlements because of the provisions whereby the generics agreed not to relinquish their 180-day exclusivity period. Such provisions acted to prevent other potential competitors, even those not involved in the agreements, from being able to enter the market.<sup>249</sup> Furthermore, the agreements prevented the potential entrant from marketing not only the generic at issue in the infringement case, but also any other generic, regardless of whether it infringed on the brand name drug involved.<sup>250</sup> Finally, the agreements contained payments that in effect constituted

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<sup>245</sup> See *id.*

<sup>246</sup> See *id.*

<sup>247</sup> See discussion *supra* Part IV.

<sup>248</sup> See Balto, *supra* note 5, at 334-35.

<sup>249</sup> See *id.*

<sup>250</sup> See *id.*

the transfer of monopoly profits from the patent holder to the alleged infringer in exchange for the ability to maintain the monopoly.<sup>251</sup> Although some might argue that the settlement agreements at issue were really nothing more than stipulated preliminary injunctions, Former FTC Commissioner Sheila Anthony has pointed out several reasons why the FTC rejected this view. In the first place, a preliminary injunction usually lasts only through the conclusion of the trial court level.<sup>252</sup> However, the agreements the FTC challenged were to be effective through the entire appeals process all the way up to the Supreme Court level. Secondly, many of the agreements the FTC challenged involved non-refundable payments. A preliminary injunction, on the other hand, usually only requires the moving party to post a bond to cover damages to the enjoined party should that party win.<sup>253</sup> Thirdly, a preliminary injunction in a patent infringement case would only be applicable to the potentially infringing product whereas many of the settlements at issue contained restrictions on non-infringing products as well.<sup>254</sup> In addition, the settlements prevented the generic drug company from relinquishing its 180-day exclusivity period or from transferring it to another party.<sup>255</sup> Finally, these agreements were not subject to the same type of judicial review to which preliminary injunctions are subject.<sup>256</sup> Whereas judges considering a preliminary injunction weigh the public interest and the likelihood of success on the merits, no such balancing occurs with these private settlements.<sup>257</sup>

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<sup>251</sup> See *id.*

<sup>252</sup> See Anthony, *supra* note 123. Although Commissioner Anthony was specifically referring to the case involving Abbott and Geneva, the rationale is equally applicable to other patent settlement cases with similar terms.

<sup>253</sup> See *id.*

<sup>254</sup> See *id.*

<sup>255</sup> See *id.*

<sup>256</sup> See *id.*

<sup>257</sup> See *id.*



## VI.

### Possible Solutions

As these recent FTC cases demonstrate, the regulatory structure of the Hatch-Waxman has loopholes that enable innovator drug companies in the pharmaceutical industry to exploit the Act's patent provisions to the possible detriment of consumers. As one of the authors of the act has noted, "The law has been turned on its head. We were trying to encourage more generics and through different business arrangements, the reverse has happened."<sup>258</sup>In light of the costs that patent settlements exploiting these loopholes may impose on consumers, policymakers increasingly have called for changes to or the total repeal of the Hatch-Waxman Act. However, any attempt to change or repeal the Act must take into consideration the impact that the Act has had on the pharmaceutical market as a whole instead of just looking at the effects that patent settlements have had on the market for particular drugs.

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<sup>258</sup>Sheryl Gay Stolberg and Jeff Gerth, *Drug Makers' Deals Swallow Competition*, N.Y. TIMES, July 23, 2000.

A.

## The Impact of the Hatch-Waxman Act on the Pharmaceutical Industry

1.

### The Impact of the Hatch-Waxman Act on Competition

Since the passage of the Hatch-Waxman Act, the United States has seen an increasingly competitive generic market. In 1983 among the top two hundred pharmaceutical companies, thirty-four of the fifty-two drugs produced by these companies that had expired patents (approximately sixty-five percent) had no generic competitors.<sup>259</sup> However, when the Congressional Budget Office conducted a survey on the effects of the Hatch-Waxman Act in 1998, the number of generic drugs available to consumers had increased such that generics were available for almost all of the top selling drugs with expired patents.<sup>260</sup> In 1984, only nineteen percent of the prescription drugs sold in the United States (measured in “total countable units” such as tablets or capsules) were generic drugs.<sup>261</sup> By 1996, forty-three percent of all prescription drug units sold in the United States were generic drugs.<sup>262</sup> Thus, the period since 1984 has seen growth in the generic market both in terms of an increase in the number of generic drugs available to consumers and in terms of the percentage of prescriptions filled with generic drugs.

The result of increased competition from the generic market has been a decrease in the costs to consumers.

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<sup>259</sup> See Grabowski, *supra* note 61, at 195-96.

<sup>260</sup> See CBO STUDY, *supra* note 1.

<sup>261</sup> See *id.* Countable units do not include injectable drugs and liquid forms of drugs, therefore, this percentage does not represent a perfect measure of generic market share. See *id.*

<sup>262</sup> See *id.* The CBO Study attributes some of this growth in the generic market to the passage of state drug-substitution laws which allow pharmacists to substitute a generic drug for a brand name drug regardless of what the prescription says and to the promotion of generic substitution by certain government health programs like Medicaid and by many private health insurance plans. However, the CBO considers the Hatch-Waxman Act to be a major contributor to the increase in the generic market. See *id.*

In a look at twenty-one different brand-name prescription drugs, the Congressional Budget Office found that the brand-name drugs on average lost forty-four percent of their market to generic drugs within the first full calendar year after patent expiration.<sup>263</sup> While this loss of market share generally does not cause brand name drugs to lower their prices,<sup>264</sup> generics decrease the costs to consumers by offering lower priced alternatives to the brand-name drugs.

Generics also decrease costs to consumers by competing among themselves. In general, the first generic drug manufacturer to enter a market usually charges only about seventy to eighty percent of what an innovator drug manufacturer charges for its product.<sup>265</sup> When there are between one and ten firms marketing generic versions of the brand-name drug, the generic retail price of a drug averages around sixty percent of the price of the comparable brand-name drug.<sup>266</sup> If more than ten manufacturers enter the market, the average generic prescription price falls even further to less than fifty percent of the brand-name price.<sup>267</sup> The cost savings that have resulted from the ability to use generics as a substitute for brand-name products and from the competition between generics have been substantial to consumers. The Congressional Budget Office estimates that in 1994 alone, consumers saved between eight and ten billion dollars by purchasing generic drugs instead of the more expensive pioneer versions. In 1994, the average price of a prescription for a brand-name drug was thirty-seven dollars.<sup>268</sup> By including prescriptions filled with a generic drug in

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<sup>263</sup> See *id.*

<sup>264</sup> See *id.*

<sup>265</sup> See Molly Boast, Director, Bureau of Competition, Prepared Statement of the Federal Trade Commission Before the Committee on the Judiciary, United States Senate, Competition in the Pharmaceutical Marketplace: Antitrust Implications of Patent Settlements (May 24, 2001), available at <http://www.ftc.gov/os/2001/05/pharmstmy.htm>.

<sup>266</sup> See CBO STUDY, *supra* note 1.

<sup>267</sup> See *id.*

<sup>268</sup> See *id.*

that figure, the average price is only twenty-six dollars.<sup>269</sup> This means that generic substitution has lowered the average cost of prescriptions by eleven dollars. Thus, the conclusion is that the Hatch-Waxman Act has indeed achieved its goals of aiding the generic market and as a result, of obtaining lower prices for consumers.

## 2.

### **The Impact of the Hatch-Waxman Act on Incentives to Innovate**

Despite increasing the amount of competition within the pharmaceutical industry, the Hatch-Waxman Act does not seem to have significantly decreased the incentives for innovation. According to the Congressional Budget Office's study, the FDA approved 101 drugs containing new chemical compounds between 1992 and 1995. For the fifty-one of those drugs that received a patent extension,<sup>270</sup> the average extension lasted 2.9 years.<sup>271</sup> As a result, the average length of time between market entry and patent expiration for an innovator drug has increased from nine years in 1984 to eleven to twelve years today.<sup>272</sup> At the same time that patent life has increased by almost three years, the average time between patent expiration and generic entry has gone from three years to almost immediate entry.<sup>273</sup> Since these three-year periods almost exactly offset each other, the Hatch-Waxman Act has not really changed the average point in a drug's life at which generic

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<sup>269</sup> *See id.*

<sup>270</sup> Of the 101 drugs examined by the CBO, fifty-one received Hatch-Waxman extensions, twelve still had applications pending for an extension, nineteen had no patent to extend, fifteen already had fourteen years of patent life left and thus could not receive further extension, and four did not apply for an extension. *See id.*

<sup>271</sup> *See id.* This figure includes those drugs subject to the two-year transitional cap for drugs undergoing clinical testing when the Hatch-Waxman passed. Excluding those drugs, the average extension lasted 3.0 years. *See id.*

<sup>272</sup> *See id.*

<sup>273</sup> *See id.*

entry occurs.<sup>274</sup> Even though the Hatch-Waxman Act has not had a substantial effect on the point at which generic entry occurs, as noted in the previous section, the Act did change the likelihood that generics would become available as well as the average market share captured by generics. According to the Congressional Budget Office's study, this increased market share has reduced the present discounted value of returns for an innovator drug by an average of about twenty-seven million dollars.<sup>275</sup> This represents a decline in expected returns of about twelve percent.<sup>276</sup> However, based on the figures on the costs of bringing a drug to market that the Congressional Budget Office used,<sup>277</sup> the level of returns from innovator drugs are still able to fully cover the capitalized costs of research and development.<sup>278</sup> Since the passage of the Hatch-Waxman Act, both the amount received from the sale of prescription drugs and the amount spent on research and development has grown. Between 1985 and 1995, the sales from prescription drugs increased from \$21.6 billion to \$60.7 billion, representing an increase from 5.7% to 6.9% of total health care expenditures.<sup>279</sup> In fact, the sale of prescription drugs grew faster than the total health care spending during that period.<sup>280</sup> During the same period, spending on research and development increased from 15.1% to 19.4% of brand-name sales.<sup>281</sup> Thus despite the pressures from a growing generic market and the decreased returns from innovation, the rise in spending on research and development indicates that the Hatch-Waxman Act has not destroyed the incentive for investing in innovation.

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<sup>274</sup> See *id.*

<sup>275</sup> See *id.*

<sup>276</sup> See *id.*

<sup>277</sup> At the time of the CBO study, manufacturers of innovator drugs were estimated to invest \$200 million on average to bring a new drug to market. For drugs introduced in the early 1980's, earned returns exceeded the capitalized costs of development by twenty-two to thirty-six million dollars. See *id.*

<sup>278</sup> See *id.*

<sup>279</sup> See *id.*

<sup>280</sup> See *id.*

<sup>281</sup> See *id.*

## **B.**

### **Possible Solutions to the Problems Created by Patent Settlements in the Pharmaceutical Industry**

Because the Hatch-Waxman Act has enabled the generic market to grow significantly without destroying the incentives for innovation in the process, total repeal of the Hatch-Waxman Act in order to avoid some of the anticompetitive issues that arise in the context of patent settlements seems quite extreme. Instead, policy makers should look for ways to revise the Hatch-Waxman Act so as to preserve the beneficial aspects of the statute. There are two different types of approaches that could be used – amending the Hatch-Waxman Act so as to eliminate some of the loopholes or creating stricter regulations to govern pharmaceutical companies that wish to settle patent disputes.

#### **1.**

##### **Amending the Hatch-Waxman Act**

###### **a)**

##### **Adding a Triggering Period to the 180-day Exclusivity Rule**

One way to avoid many of the anticompetitive effects of patent settlements would be to alter the 180-day exclusivity period. The FDA has already made such a proposal in part to address the issues that arise

because of settlement and licensing agreements between innovator and generic drug manufacturers.<sup>282</sup> Under the FDA's proposed rule, the FDA would place a time limit on how long the ANDA first filer has to trigger its right to receive the 180-day marketing exclusivity period.<sup>283</sup> The triggering period would involve a "use it or lose it" provision in which a first filer would have 180 days to start the 180-day marketing period or else the first filer loses the right to the 180 days of marketing exclusivity.<sup>284</sup> The triggering period would begin once a second generic drug company with a Paragraph IV certification receives tentative FDA approval and would require the first filer to either obtain a favorable final court decision or to begin commercial marketing of its generic.<sup>285</sup> However, there are three instances in which the triggering period would not begin to run on the date of the second filer's tentative approval. If the first filer was involved in an ongoing patent infringement litigation regarding the Paragraph IV certification, the triggering period would not begin until the end of the thirty day stay.<sup>286</sup> Second, if a court has issued a preliminary injunction preventing the first filer from commercially marketing the drug, then the triggering period does not commence until the preliminary injunction ends.<sup>287</sup> Finally, the triggering period will not begin until the expiration of the statutorily described exclusivity period for the listed drug.<sup>288</sup> The implementation of a triggering period would help close up some of the loopholes in the Hatch-Waxman Act because it would reduce the ability of patent settlements to delay generic entry into the market.<sup>289</sup> First, a triggering period would insure that competition commences

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<sup>282</sup> See 180-Day Generic Drug Exclusivity for Abbreviated New Drug Application, 64 Fed. Reg. 42873, 42880 (August 6, 1999) (to be codified at 21 C.F.R. pt. 314).

<sup>283</sup> See *id.* at 42873.

<sup>284</sup> See *id.* at 42877.

<sup>285</sup> See *id.*

<sup>286</sup> See *id.*

<sup>287</sup> See *id.*

<sup>288</sup> See *id.*

<sup>289</sup> See *id.* at 42880.

soon after a pioneer's patent expires if there is a generic company that has received FDA approval for its ANDA. Either the first filer will get to market quickly and provide competition for the pioneer drug, or else another generic will be able to enter the market to compete with the pioneer drug. Second, by placing the triggering event in the hands of another party, the innovator drug company and the generic drug company no longer have the ability to use an agreement to control entry into the market. Thus, the triggering period would have an overall positive effect on competition.

b)

### **Eliminating the 180-day Exclusivity Rule**

An alternative to adding a triggering period to the 180-day exclusivity rule would be to eliminate the rule entirely. The 180-day exclusivity period was included to reward those first filers to challenge pioneer drug companies patents. However, at the time this provision was included in the Hatch-Waxman Act, the drafters “foolishly believed that patent challenges would only arise in cases where the validity of a basic patent was at issue, that there was no realistic possibility that such cases could be settled, and that litigation would be expensive.”<sup>290</sup> Instead, experience has shown that the “potential profit from a successful challenge far exceeds the cost of litigation and risk can and has been minimized by careful selection of meritorious cases as well as the real possibility of settlement.”<sup>291</sup> Arguably then, the 180-day exclusivity period is no longer even necessary in order to stimulate the generic market. By eliminating the period entirely, multiple generics could enter the market at one time, thus leading to more vigorous competition and lower prices for consumers.

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<sup>290</sup> Alfred B. Engelberg, *Special Patent Provisions for Pharmaceuticals: Have They Outlived Their Usefulness?*, 39 IDEA: J.L. & TECH. 389, 423 (1999).

<sup>291</sup> *Id.*



c)

### **Eliminating the Thirty Month Injunction**

Another possible way to end some of the abuses that occur in patent settlements would be to eliminate the thirty-month automatic injunction that takes effect when a pioneer drug company files a patent infringement suit against a generic drug company which has provided Paragraph IV certification. In fact, this suggestion has been included in the Greater Access to Affordable Pharmaceuticals Act of 2001, a proposed amendment to the Federal Food Drug and Cosmetic Act that was introduced in both the House of Representatives and the Senate in May 2001.<sup>292</sup> Eliminating the automatic injunction would be beneficial to competition in several ways. First, eliminating the thirty-month automatic injunction would allow frivolous or invalid patents to be challenged more quickly.<sup>293</sup> Second, elimination of the thirty-month automatic injunction would take away the incentive for pioneer drug companies to delay competition from generics by filing patent infringement cases that do not have any merit. Those pioneer drug companies that do have a meritorious claim would not be harmed because they could still go to court and obtain a preliminary injunction against the generic company. Third, because a pioneer drug company would have to demonstrate a reasonable likelihood of success on the merits in order to a preliminary injunction,<sup>294</sup> there would be reduced incentive for the pioneer to settle. A pioneer drug company whose patent claims have been deemed strong enough by a court to merit a preliminary injunction would have much less reason to share its profits with a generic and the generic would have much less bargaining power to induce the pioneer into a settlement. Finally, if a court does not grant a pioneer a preliminary injunction there would be less of an incentive for a generic to enter into a settlement since it

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<sup>292</sup>See Greater Access to Affordable Pharmaceuticals Act, S. 812, 107<sup>th</sup> Cong. (2001); Greater Access to Affordable Pharmaceuticals Act, H.R. 1862, 107<sup>th</sup> Cong. (2001). These bills have been referred to the Subcommittee on Health of the House Committee on Energy and Commerce and to the Senate Committee on Health, Education, Labor, and Pensions.

<sup>293</sup>See William Nixon, *Hatch-Waxman Reform Will Benefit Industry and Patients*, DRUG STORE NEWS, August 20, 2001.

<sup>294</sup>See *supra* note 257 and accompanying text.

could go to market immediately upon receiving FDA approval. Regardless, “the absence of an automatic thirty-month injunction will serve to compel the parties to expedite the litigation process as a matter of mutual self-interest in getting an early definitive court ruling on the merits.”<sup>295</sup>

## 2.

### Stricter Regulation of Patent Litigation

#### a)

#### Require Parties to File Patent Settlements with the Government

In addition to amending provisions of the Hatch-Waxman Act, another potential avenue for policymakers to explore is stricter regulation of patent litigation. One proposal offered by then Acting Assistant Attorney General Joel Klein was to expand the Hart-Scott-Rodino Premerger Notification Act<sup>296</sup> to require that patent settlements be filed with the antitrust authorities.<sup>297</sup> The Patent Code currently requires parties to file patent interference settlements with the Patent and Trademark Office and allows the Antitrust Division to obtain these filings for review.<sup>298</sup> However, it is questionable whether this provision could ever actually be effective in dealing with anticompetitive issues because the Third Circuit has held that the statute does not

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<sup>295</sup>Engelberg, *supra* note 290, at 422.

<sup>296</sup>The Hart-Scott-Rodino Act requires parties involved in a merger to provide advance notice to the FTC and the Antitrust Division of the Department of Justice if the size of the transaction and parties exceeds certain thresholds. The FTC and the Antitrust Division then analyze the transactions to determine whether there are anticompetitive issues (usually a substantial lessening of competition or a tendency to create a monopoly) that merit enforcement action. See Kevin J Arquit & Richard Wolfram, *Mergers and Acquisitions: United States Government Antitrust Analysis and Enforcement*, 86 PLI/NY 465, 471 (Nov. 2000) (discussing the Hart Scott Rodino Antitrust Improvements Act of 1976, Clayton Act §7A, 15 U.S.C. §18a (1988)).

<sup>297</sup>See Joel I. Klein, Acting Assistant Attorney General, Antitrust Division, U.S. Department of Justice, Crossed Licensing and Antitrust Law, Address Before the American Intellectual Property Law Association (May 2, 1997), *available at* <http://www.usdoj.gov/atr/public/speeches/1123.htm>.

<sup>298</sup>See 35 U.S.C. §135(c) (2001).

provide the Antitrust Division with standing to enforce it.<sup>299</sup> Enacting a separate requirement that parties file settlements with the antitrust authorities would allow the antitrust authorities to “assess what is at stake for competition in the matter while it is pending, putting [antitrust authorities] in a position to decide quickly and...confidently when confronted with a settlement.”<sup>300</sup> The benefit to Klein’s proposal is that the antitrust authorities could either try to block an anticompetitive settlement on public interest grounds or take over the defendant’s role and continue forward with the litigation.<sup>301</sup> However, critics of the proposal have questioned where the antitrust authorities would get the resources to do these reviews and to what extent antitrust authorities are equipped to determine the validity of patents.<sup>302</sup> An alternative to Joel Klein’s proposal, one which was suggested by the FTC in a “Comment” with the FDA, was that the FDA require innovator and generic drug companies to file patent litigation settlements with the FDA.<sup>303</sup> The FDA would then make these settlements accessible to the FTC.<sup>304</sup> The proposal is similar to Joel Klein’s proposal in that it would create a system of filing that would “assure better detection of anticompetitive arrangements that harm consumer welfare.”<sup>305</sup> However, this proposal is subject to the same criticism as Joel Klein’s in that it raises resource and capability issues.

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<sup>299</sup>See *U.S. v. FMC Corp.*, 717 F.2d 775, 787 (3d Cir. 1983).

<sup>300</sup>See *id.*

<sup>301</sup>See Mary L. Azcuenaga, *Address to Boston University School of Law: Recent Issues in Antitrust and Intellectual Property*, 7 B.U. J. SCI. & TECH. L. 1, 21 (2001).

<sup>302</sup>See *id.*

<sup>303</sup>See Comment of the Staff of the Bureau of Competition and of Policy Planning of the FTC Before the FDA, *In re. 180-Day Generic Exclusivity for Abbreviated New Drug Applications* (Nov. 4, 1999), *available at* <http://www.fda.gov/ohrms/dockets/dailys/110899/c000059.pdf>.

<sup>304</sup>See *id.*

<sup>305</sup>*Id.*

b)

### **Require Parties to File Settlements with the Courts**

Another potential way to provide for better regulation of patent conflicts between pioneer and generic drug manufacturers would be to require all pioneer and generic drug manufacturers to file patent settlements for approval by a court. This was the approach taken in both the consent order involving Abbott and Geneva and the consent order involving Hoechst MRI and Andrx Corporation, which required the involved parties to file any future patent settlements for court approval.<sup>306</sup> However, both the Abbott case and the Hoechst MRI case involved interim settlements in the context of litigation. Any requirement that settlements obtain court approval would also need to apply to final settlements reached prior to litigation in order to prevent parties from circumventing the requirement by trying to settle a case without ever filing a patent infringement suit. The downside to such a requirement, however, is that courts may be reluctant to give what would basically amount to an advisory opinion on issues that the parties have been able to agree upon.<sup>307</sup> Also, going through the process of court approval would add additional time and expense to the settlement process, thus reducing some of the benefits traditionally associated with settling litigation.

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<sup>306</sup> See Consent Order at ¶3, Abbott Labs. And Geneva Pharms., Inc. (2000) (Docket No. C-3945); Consent Order at ¶ 3, Hoechst Marion Roussel, Inc., Cardem Capital L.P., and Andrx Corp. (2000) (Docket No. 9293).

<sup>307</sup> See Leary, *supra* note 107.

## VII.

### Conclusion

The entire premise behind the Hatch-Waxman Act was to encourage competition in the pharmaceutical industry while at the same time preserving incentives to innovate. Even though the Act is not able to perfectly balance these two goals in its current form, policymakers should be mindful not institute changes which will disturb the balance even further. Based on this consideration, the best way to deal with the anticompetitive issues that have arisen during the course of patent settlements is by combining several of the proposals discussed in the previous section. Specifically, the best course for policymakers would be to eliminate the 180-day exclusivity period, eliminate the thirty-month automatic stay, and require pharmaceutical companies to file patent settlements with the antitrust authorities.

At the time the Hatch-Waxman Act was passed, policymakers assumed that the 180-day exclusivity period was needed in order to provide incentives for generic drug companies to undertake the costly, risky process of challenging the validity of an innovator drug company's patents.<sup>308</sup> However, this assumption ignored the fact that the FDA relies on the assertions of innovator drug companies with regard to the validity of their patents.<sup>309</sup> Given that many innovator drug companies file patents of questionable validity in order to maintain market exclusivity, generic drug companies actually have a high probability of succeeding at challenges to an innovator's patents. This high probability of victory should be enough of an incentive for generic manufacturers to challenge patents such that the 180-day exclusivity period is not really even a needed incentive. Therefore, eliminating the 180-day rule would not have an anticompetitive effect.

In fact, not only would elimination of the 180-day exclusivity rule not have an anticompetitive effect, it would

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<sup>308</sup> See discussion *supra* Part III.B.1.

<sup>309</sup> See *id.*

actually be a pro-competitive move. By eliminating the rule, policymakers would take away the ability of either an innovator or a first filer to keep other potential competitors off the market. The data clearly shows that the more generic competitors there are in a market, the lower the amount that consumers are forced to spend on prescription drugs.<sup>310</sup> Thus, allowing more than one competitor to enter the market immediately following the expiration of a pioneer's patents would result in consumer savings.

Policymakers assumed that the thirty-month automatic stay which takes effect when a pioneer drug company files a patent infringement suit upon receiving a Paragraph IV certification was necessary in order to counterbalance the possible negative effects on innovation that the shortened ANDA process might create. Again, however, policymakers ignored the fact that pioneer drug companies might file questionable patents. In the case of an invalid patent, the thirty-month stay actually does nothing other than prolong the harm to competition that results from protecting products unworthy of intellectual property protection. Innovator drug companies that actually have meritorious claims would not be harmed by elimination of the automatic injunction because they could go to court and obtain a preliminary injunction.<sup>311</sup> The preliminary injunction mechanism would protect incentives to innovate in the exact same way that the thirty-month automatic stay would. Furthermore, elimination of the automatic stay would reduce the incentives that both innovators and generics have for entering into potentially harmful anticompetitive settlements.<sup>312</sup> Thus, competition would be helped but not at the expense of innovation.

Because eliminating the 180-day exclusivity rule and the thirty-month automatic stay will not eliminate all of the anticompetitive problems that often arise in patent settlements, pharmaceutical companies should also be required to file any patent settlements with the antitrust authorities. This requirement could be imposed by amending the Hart-Scott-Rodino Premerger Notification Act, thereby giving the FTC and the Antitrust

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<sup>310</sup> See *supra* notes 265 - 267 and accompanying text.

<sup>311</sup> See discussion *supra* Part VI.B.1.c.

<sup>312</sup> See *id.*

Division of the Department of Justice the power to enforce the requirement. A filing requirement would be beneficial for several reasons. The knowledge that any settlement will undergo review by the antitrust authorities should act as a deterrent to prevent parties from trying to include settlement provisions that clearly fly in the face of the antitrust laws. The filing requirement would also enable antitrust authorities to keep an eye out for other strategies that pharmaceutical companies use to exploit loopholes in the Hatch-Waxman regulatory structure. For those strategies with questionable effects on competition, the antitrust authorities would have the opportunity to analyze the competitive risk and challenge the settlement if it is deemed harmful to consumers.

In order to help offset the costs associated with the review of these filings, parties could be required to pay a filing fee. Although the fee and the additional work involved with making the filing would add costs to the settlement process that are likely to be passed on to consumers, these costs should be somewhat offset by the benefits that accrue to consumers from not having patent settlements which inhibit competition.

Regardless of what changes, if any, are made to the Hatch-Waxman Act in the coming years, it is likely that anticompetitive issues within the pharmaceutical industry will continue to arise. Just recently, Timothy Muris, Chairman of the FTC, testified before Congress about competition in the pharmaceutical industry, specifically with respect to the operation of the Hatch-Waxman Act.<sup>313</sup> In his testimony he noted that the FTC, while continuing to litigate patents settlements between pioneer drug companies and innovator drug companies, has progressed to a “second generation” of litigation to insure vigorous competition in the pharmaceutical industry.<sup>314</sup> This second generation of litigation involves such practices as improper listing

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<sup>313</sup> See Muris, *supra* note 2.

<sup>314</sup> *Id.*

of patents in the Orange Book and settlements between two generics.<sup>315</sup> As this new wave of litigation demonstrates, where there are profits to be had, drug companies will find new loopholes to exploit. While the recommendations in this paper can help eliminate some of the current abuses, they will not eliminate the need for rigorous antitrust enforcement in the pharmaceutical industry. Ultimately, it is probably only through this type of rigorous enforcement that the Hatch-Waxman Act's goal of balancing incentives to innovate with robust generic competition can be achieved.

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<sup>315</sup> *See id.*